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Delivering Acceptance and Commitment Therapy (ACT) for Mental Health Disorders Across Group and Guided Self-Help Formats: A Meta-Analysis and Randomised Controlled Trial.

Doctoral Thesis

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Doctorate in Clinical Psychology

The University of Edinburgh

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Dedications

To my wife, Nicola, for her patience and for giving me the time and space to be able to write this thesis. To my son, Isaac, for being the inspiration for all that I do. To my family, for all their support and encouragement over the years which has allowed me to help others.

In loving memory of Dr Fara McAfee. Your time, knowledge and experience has enabled me to become the psychologist that I am today.

Table of Contents

List of Figures & Tables

Systematic Review & Meta-analysis

Empirical Study

Appendix

Overall word count: 18,657

Overall Abstract

Background: Acceptance and Commitment Therapy (ACT) has shown promise as an effective intervention in the treatment of mental health disorders. In the last decade, the delivery of ACT has expanded to include various formats (e.g. groups, self-help, online and phone apps). Further research is needed to evaluate whether such delivery formats are a viable extension of ACT. Furthermore, the existing evidence base of certain alternative delivery formats have yet to be reviewed. This thesis portfolio sought to contribute to this area of research.

Methods: A systematic review of the literature was conducted to investigate the efficacy of group-based interventions for mental health disorders using ACT. Five databases were systematically searched, manual searches were conducted and corresponding authors were contacted. Studies which used a randomised-controlled design, with adult samples and investigated group-based ACT interventions for mental health disorders were included. A meta-analysis of the included studies was conducted for post-intervention and follow-up data.

In the empirical study, an ACT manual was trialled using a randomised-controlled design to investigate the efficacy of using ACT in a guided self-help context. Participants with anxiety/depression were randomly assigned to receive either the ACT intervention or treatment as usual (TAU). Those in the ACT group were posted an ACT manual and received two telephone calls. Outcome measures were analysed after the six-week intervention.

Results: From the meta-analysis, 18 randomised-controlled trials were identified, 14 of which focussed on anxiety and depression. The findings suggest that ACT-

based groups have a large effect on symptom reduction when compared to non-active comparisons at post-treatment and a moderate effect when compared to non-active comparisons at follow-up. Additionally, there was a small effect in favour of ACT when compared to active treatment controls at post-treatment and equivalent effects when comparing ACT to active treatment controls at follow-up. Similar effects were found when separately comparing the 14 studies which focussed primarily on anxiety and depression.

The empirical study revealed that guided self-help was found to be no more effective in improving quality of life or reducing psychological distress than the TAU group. However, such results should be interpreted with caution as the small sample size and high attrition rate indicates that further research with larger samples and follow-up are needed before strong conclusions can be made.

Conclusions: The findings of this research indicate that group-based ACT interventions may be a suitable alternative delivery format for service providers in the provision of common mental health disorders, particularly anxiety and depression. Further research is needed before any strong conclusions can be made regarding the efficacy of guided self-help for anxiety/depression.

Lay Summary of Thesis

Acceptance and Commitment Therapy (ACT) is a new therapy that has been shown to be effective in treating individuals with a variety of mental health issues. However, there is still a substantial amount of research that needs to be conducted, especially with regards to how well ACT works in alternative delivery formats, such as a group treatment or in guided self-help formats.

The first part of this thesis aimed to review how effective ACT was in a group format, by gathering the results from previously conducted studies and reporting their overall effects. The review found 18 relevant studies, from several databases, that focussed on delivering ACT in a group format. Anxiety and depression were found to be the two most prominent mental health conditions that studies aimed to treat in a group format. The findings suggest that using ACT-based groups to treat mental health disorders (mainly anxiety and depression) were very effective, compared to receiving no treatment at all and as effective as using other types of therapies to treat the same conditions. This was the case at the end of treatment as well as several weeks after the intervention. Overall the review suggests that delivering ACT in a group format may be an acceptable treatment method.

The second part of the thesis aimed to investigate how effective ACT is in a guided self-help format by trialling a manual for individuals with anxiety/depression. Forty-nine individuals were randomly divided into two groups. One group received the ACT manual as well as two telephone calls from a therapist to guide them through the manual. The other group received no treatment. The results showed that there was no significant difference in those who completed the ACT guided self-help intervention compared to the individuals who received no treatment. Several

explanations are considered as to why such results were observed. The study suffered from a small sample size which is arguably the main reason for such results. Alternatively, a null result may indicate that such sample needs more intensive therapies than guided self-help.

Part A: Systematic Review & Meta-Analysis

The Clinical Efficacy of Group-based Interventions for Mental Health Disorders using Acceptance and Commitment Therapy (ACT): A Systematic Review and Meta-analysis of Randomised Controlled Trials.

Prepared for submission to the

Journal of Contextual Behavioral Science

(See Appendix 6 for the journal's *Guide for Authors*)

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The Clinical Efficacy of Group-based Interventions for Mental Health Disorders using Acceptance and Commitment Therapy (ACT): A Systematic Review and Meta-analysis of Randomised Controlled Trials.

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1.0 Highlights

- Eighteen randomised-controlled trials were systematically reviewed.
- Most included studies focussed on anxiety and depression.
- There were a range of biases across studies.
- A meta-analysis indicated that group-based ACT produced improvements in symptoms.
- The current evidence was limited to specific mental health conditions.

2.0 Abstract

Background: Acceptance and Commitment Therapy (ACT) has shown promising results in the treatment of common mental health disorders. In the last decade, the delivery of ACT has expanded to include various delivery formats (e.g. individual, group, self-help, online and phone apps). The efficacy of ACT when conducted in the context of group formats has not yet been systematically reviewed.

Objective: To summarise the efficacy of delivering ACT in group formats to adults with mental health disorders, when compared to active and non-active control conditions.

Search Methods: PsychINFO, Medline, EMBASE, the Cochrane Controlled Trials Register and the Cumulative Index to Nursing Allied Health Literature databases were systematically searched from inception to April 2016, and then repeated up until January 2017. Additional studies were identified by contacting relevant authors in the field, manually screening references as well as selected journals and searching the Association of Contextual Behavioural Science's publication database.

Selection Criteria: Randomised controlled trials studying the efficacy of group-based interventions, for mental health disorders were included. Adults over the age of 18 were included, with no restrictions on demographic variables. A variety of valid and reliable mental health outcomes were considered (symptom and function-based).

Study appraisal and synthesis methods: Risk of bias was assessed using an adapted version of the *Quality assessment tool for quantitative studies* (EPHPP, 1998). Cochran's Q statistic, I^2, and funnel plots were utilised to assess heterogeneity and publication bias.

Results: Eighteen studies (n = 983) were identified. Most studies focused on depression and anxiety. Overall, the evidence suggests that group-based ACT is as efficacious as active interventions (g = -0.25) and more efficacious than non-active intervention comparisons (g = -0.91) at post-treatment. At follow-up ACT-based

groups remained more efficacious than non-active treatments (g = -0.63) and were equivalent to active comparisons (g = -0.18).

Limitations: This review highlights the need for additional randomised controlled trials to evaluate the efficacy of group-based ACT in more diverse mental health disorders. Some included studies were of low methodological quality and suggestions were made to improve this. Symptom-based outcomes were the only type of outcomes identified, therefore further studies may wish to use alternative outcome measures, such as values-based or quality of life measures.

Conclusions: The findings of the review indicate that group-based ACT may be an efficacious intervention for anxiety and depression, with emerging evidence for other mental health disorders.

Registration number: CRD42016037140 (Prospero International Prospective Register of Systematic Reviews).

Keywords: Acceptance and Commitment Therapy, Group Therapy, Mental Health, Systematic Review, Meta-analysis

3.0 Introduction

Globally, mental health disorders affect one in four individuals across a lifetime (WHO, 2001). This accounts for around 450 million people worldwide. Mental health disorders have significant adverse effects on individuals, including social exclusion (Sayce, 2001), financial hardship, and unemployment (Leff & Warner, 2006). An estimated 800,000 people commit suicide every year, making it the second

leading cause of death in young adults (WHO, 2014). In the UK, the Aviva Health of the Nation (2013) survey found that 202 general practitioners reported that 84% of patients sought consultation for stress and anxiety, as well as 55% reporting other mental health issues. The Care Quality Commission report (2015) revealed that three million adults were registered with depression in England alone. As demand for treatment increases, services around the world are struggling to meet such need in a timely manner. One in ten individuals with a mental health disorder in the UK reported waiting more than a year to receive a talking therapy (Mind, 2013). The World Health Report, 'New Understanding, New Hope' (2001) recommends improved service provision, allowing greater access to psychological therapies. To achieve this, traditional ways of delivering therapies (i.e. one-to-one therapy) may need to be reconsidered to accommodate for the growing volume of individuals seeking help.

3.1 Delivering therapy in group formats

One such approach to delivering therapy more economically is to provide group-based interventions. In this instance, multiple individuals can receive the same therapy simultaneously. Group therapies brings various advantages for both the patient and therapist. For the patient, group therapies can create a sense of universality; helping patients to realise they are not alone in their struggles (Yalom, 2005). Therapeutic groups can also offer social support, whereby patients can learn from others, and help each other recover (Yalom, 2005). Heimberg, Salzman, Holt and Blendell (1993) suggest group members can act as 'co-therapists', challenging patients to make changes. Additionally, Hollon & Shaw (1979) argue that the views of other group members can carry more weight than the facilitator themselves.

For service providers, group therapies can "offer economies of scale" (Whitfield, 2010; p. 219). The time needed for intervention can be easily quantified and group work can reduce service demand, where clinically appropriate (The Mental Health Collaborative, 2010). Although time to treatment can be reduced though the use of groups, not all group-based interventions offer cost-effective solutions. Tucker and Oei (2007) evaluated 36 studies comparing the cost effectiveness of individual cognitive-behavioural therapy (CBT) to group CBT. They concluded that group CBT for depression was more cost-effective than individual CBT but less so for anxiety disorders.

Research has shown that group therapy may achieve clinical improvement through different mechanisms to that of individual therapy. For example, Hedman et al., (2013) found that improvement from group CBT for social anxiety disorder was mediated by changes in anticipatory and post-event processing. In contrast, improvement from individual-based CBT was mediated by reductions in avoidance as well as self-focussed attention. This suggests that individual and group therapies using the same intervention modality may work through different mechanisms based on treatment format. Group treatments could have benefits over individual therapies depending on which target mechanisms are important for change.

A criticism of using group-based interventions is that they provide a sub-optimal treatment choice (Rush & Watkins, 1981). Nonetheless, a review consisting of 26 studies comparing CBT in a group format to individual CBT showed that, for most mental health disorders, group CBT was similarly efficacious as individual therapy (Morrison, 2001). Research has also shown that these improvements are maintained several years later (Mörtberg, Clark & Bejerot, 2011; Hedman et al., 2014;

McCarthy, Hevey, Brogan & Kelly, 2013).

3.2 Traditional CBT vs. ACT in group contexts

Traditional CBT has been widely utilised as the psychological treatment of choice for common mental health disorders, with many randomised-controlled trials (RCTs) showing its efficacy across a broad range of disorders (e.g. Butler, Chapman, Forman, & Beck, 2006; Hofmann, Asnaani, Vonk, Sawyer, & Fang, 2012).

ACT is part of the family of cognitive and behavioural therapies. It takes a values-based approach to psychological suffering (Hayes, Levin, Plimb-Vilardaga, Villatte, & Pistorello, 2013). It promotes psychological flexibility by working on six core principles (acceptance, cognitive defusion, increasing self-as-context, clarifying values, being present and encouraging committed action; Hayes, Strosahl &Wilson, 1999). ACT provides an alternative way of approaching common mental health disorders than that of traditional CBT. It uses a functional contextual approach which predicts and influences behaviour by studying the present and historical context in which behaviour evolved. This approach diverges from traditional CBT which aims to modify dysfunctional thinking patterns and reduce unwanted sensations and emotions.

Like any emerging therapy, research into ACT seeks to find what formats it can be delivered in. So far, these have included self-help (Cavanagh, Strauss, Forder & Jones, 2014), online (Pots et al., 2016), groups (e.g. Avdagic, Morrissey, & Boschen, 2014; Lanza, García, Lamelas, & González-Menéndez, 2014; Morton, Snowdon, Gopold, & Guymer, 2012; Brassington et al., 2016) and smart technology (Barker, 2016). A growing number of studies have used ACT in a group-based format for

common mental health disorders, with promising results that have yet to be reviewed. ACT may lend itself to groups for several reasons. First, ACT takes a transdiagnostic approach meaning the same intervention can be used with little adaptation needed for specific disorders. Second, many individuals present with co-morbid conditions meaning group-based ACT may be beneficial for patients presenting with multiple difficulties, including comorbid physical health complaints. Third, ACT is process orientated, meaning diverse difficulties across individuals can be functionally addressed as reflecting the same functional process and are linked by the functional behavioural responses they elicit (e.g. cognitive fusion, experiential avoidance, lack of valued direction). Finally, the experiential nature of ACT maybe more powerful within a group setting, especially when feedback from others occurs.

A review of the published studies using ACT in a group format for the treatment of mental health disorders would describe the efficacy of a group delivery format.

4.0 Aims of review

The aim of this review was to systematically evaluate the quantitative evidence from studies using randomised controlled designs, for the efficacy of using ACT within a group format in the treatment of common mental health disorders in adults, when compared to active and non-active control conditions. It was hypothesised that ACT-based groups would be as efficacious on symptom-based reduction outcomes and more efficacious on functional improvement outcomes compared with active treatment group comparisons. Additionally, it was hypothesised that ACT-based groups would be more efficacious than non-active group comparisons on both types

of outcomes. These results were hypothesised to be evident both at post-intervention and follow-up.

5.0 Methods

This review followed the reporting guidelines from the *Preferred Reporting Items for Systematic Reviews and Meta-Analysis* (PRISMA; Mohar, Liberati, Tetzlaff, Altman, The PRISMA group, 2009). A checklist of included items can be found in Appendix 1.

5.1 Registration

The Centre of Reviews and Dissemination's *Database of Abstracts of Reviews of Effects* (DARE) was searched in March 2016, using the terms: 'acceptance and commitment therapy' OR 'ACT' OR 'CBT' AND 'group' OR 'group-based' to check whether a similar review had been written. The search revealed no results matching such criteria.

The review's protocol was specified in advance and registered online on the 22nd April 2016 with the *Prospero International Prospective Register of Systematic Reviews* (http://www.crd.york.ac.uk/prospero/display_record.asp?ID=CRD42016037140; Registration number: CRD42016037140; See Appendix 2).

5.2 Eligibility criteria

5.2.1 Types of studies

Randomised controlled trials investigating the efficacy of group-based interventions using ACT for mental health disorders were included. Other study designs (quasi-

experimental, controlled trials, uncontrolled trials and case studies) were excluded due to their potential for greater bias. Limited resources for language translation meant only those studies written in English were considered. No publication date restriction was imposed. Studies in peer-reviewed journals were included along with PhD theses that had been reviewed by independent examiners as part of a viva process.

5.2.2 Types of participants

Adults over the age of 18 were included within this review. To maximise breadth, individuals with any mental health disorder were included so long as scores on validated measures were above clinical cut-off at baseline. Studies attempting to increase positive mental health within healthy samples were excluded. Studies investigating the effects of group-based ACT for participants with physical health conditions were excluded, unless the primary outcome was on mental health disorders within such populations.

To increase clinical utility, studies with participants in inpatient, outpatient and specialist settings were included. There were no restrictions on patient demographics, such as nationality or gender.

5.2.3 Types of interventions

5.2.3.1 Experimental Intervention

An ACT group was defined as incorporating three or more components of the ACT model (acceptance, defusion, committed action, values, present moment awareness, self-as-context). Studies that only incorporated 1-2 components of ACT, such as

mindfulness-based stress reduction (e.g. Vøllestad, Sivertsen, & Nielsen, 2014), were excluded. Studies that included two or more individual sessions in addition to a group were also excluded (individual assessments and outcome collection sessions that were not part of the active treatment were included). Studies that condensed the intervention into one day (e.g. a workshop) were excluded due to the lack of a consolidation and implementation period. Mixed interventions that incorporated an additional therapeutic modality or pharmacology were excluded. Ongoing use of medication, prescribed before the intervention, were included, if that medication didn't change during the trial. Groups were defined as containing three or more participants and led by a trained facilitator (who had attended at least two ACT workshops and received supervision throughout). No restrictions on number of sessions were set.

5.2.3.2 Comparison Intervention

Active comparison interventions, as well as non-active control and placebo interventions were included. Active interventions needed to meet the criteria for groups, as stated above.

5.2.4 Types of outcome measures

A variety of different clinical outcomes were considered, depending on the mental health disorder being investigated. Studies that used a validated outcome measure of mental health, pre- and post-intervention were included. Both symptom reduction and functional improvement measures were included.

5.3 Search methods for identification of studies

For this review, the literature was searched for eligible trials in two ways:

1) Electronic Searches

a) PsychINFO (1806 – April, Week 2, 2016), Medline (1946 – April, Week 2, 2016), EMBASE (1980 – Week 17, 2016) and the Cumulative Index to Nursing Allied Health Literature (CINAHL Plus; inception to April 2016) databases were searched. The search was performed using the search terms: ('acceptance and commitment*' OR 'ACT' OR 'acceptance*' OR 'contextual behavio* science' OR '3rd wave' OR 'third wave') AND ('group*') AND ('randomi*ed controlled trial' OR 'RCT' OR 'random*' OR 'clinical trial'). No specific mental health disorder was entered so that the search would return all types of conditions which could be screened thereafter. The searches were conducted in the title, abstract and key word domains. Searches were limited to English language, 18 years and older, human sample and treatment outcome/clinical trial, where possible. The last search was run on the 22nd April 2016 and re-run in January 2017. An example of the search procedure can be seen in Appendix 3.

b) The *Cochrane Central Library of Controlled Trials* (CENTRAL) was also searched using 'acceptance and commitment' AND 'group' terms in April 2016.

c) The *Association of Contextual Behavioral Science's* (ACBS) own publication database was searched, including the 'ACT randomized

controlled trials since 1986' page in April 2016 (https://contextualscience.org/ACT_Randomized_Controlled_Trials).

2) Other searches

a) The ACBS' mailing list was used in June 2016 to contact researchers within the field about ongoing and unpublished work additional to those found from the database searches.

b) Reference lists from included studies were manually examined as well as content pages of key journals (*Journal of Contextual Behavioural Science* & *Journal of Clinical Psychology*) to identify further studies to be included.

c) All corresponding authors of the included studies were emailed about other relevant studies.

5.4 Study selection

Assessing eligibility was achieved by sequentially screening the title and abstract of each retrieved study. Articles that made no reference to randomisation, group-based therapy, acceptance and commitment therapy or mental health disorders were excluded. Ambiguous articles were read in full until it became apparent whether they were related to the criteria set for this review. This was conducted by the first author (SF).

5.5 Data collection process and data items

The Cochrane data extraction template (Cochrane Consumers and Communication Review Group, 2015) was modified for this review (see Appendix 4). Information extracted from each study included: 1) characteristics of trial participants (age,

gender, ethnicity, country, setting, clinical condition, sample size and exclusion criteria); 2) summary of interventions (including a summary of the treatment groups and facilitators); 3) outcome measures (including time points assessed and effect sizes); 4) results (including statistical methods used and a summary of the main findings). Data extraction was conducted by one reviewer (SF). Two study authors were contacted for further information (Renko & Deane, 2013; Lanza et al., 2014).

5.6 Assessment of risk of bias

The *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins & Green, 2011) and the *Scottish Intercollegiate Guidance Network* (SIGN, 2015) were consulted for guidance on assessing risk of bias in randomised controlled trials. Both guidelines revealed similar domains within their checklists. Cochrane recommended the use of either the Cochrane Collaboration's '*Risk of Bias'* tool (Higgins & Green, 2011), or the Effective Public Health Practice Project's (EPHPP) *Quality Assessment Tool for Quantitative Studies* (2004; Thomas, Ciliska, Dobbins & Micucci, 2004; Jackson & Waters, 2005). The decision was made to use a modified version of the EPHPP's *Quality Assessment Tool* for assessing risk of bias in this review, following a study by Armijo-Olivo, Stiles, Hagen, Biondo and Cummings (2012) highlighting higher reliability due to more tangible criteria, when compared to Cochrane's '*Risk of Bias'*, which requires more subjective judgements within several domains.

The *Quality Assessment Tool* is a 21-item checklist which summarises a global rating of risk of bias across six domains: selection bias, study design, confounders, blinding, data collection method and withdrawal and dropouts. It includes components of intervention integrity which may affect outcomes and has been shown

to be applicable to systematic reviews (Deeks et al., 2003). The criteria also fulfil the minimum reference standard (nine items) for RCTs, as set out in The Delphi List (Verhagen et al., 1998). Global ratings produced by this checklist comprise of, 'Strong', 'Moderate, 'Weak', and 'Unknown'. Items G and H do not form part of the global ratings scale but were included for the purposes of this review to assess intervention integrity (participant adherence) and analysis. In addition, two questions were added to the checklist, "Are the core components of the intervention implemented within the intervention?", and "Are power calculations reported and is sufficient power achieved?". The full checklist and marking criteria of the *Quality Assessment Tool* as well as how the additional items have been rated can be found in Appendix 5.

5.7 Summary measures

The primary outcome measures were the mean differences in functional improvement and symptom reduction-based outcome measures when comparing ACT groups to active and non-active comparisons.

5.8 Planned methods of analysis

Meta-analyses of continuous means were undertaken using the DerSimonian and Laird (1986) inverse variance method using MetaXL software (http://www.epigear.com/index_files/metaxl.html). Measures of consistency included the Cochran Q statistic and I^2. As this review was broad in nature, sensitivity and subgroup analyses were expected but no such analyses were pre-specified.

6.0 Results

6.1 Study selection

A total of 18 studies were identified for inclusion in this review. The initial database search revealed 3468 citations. After removing duplicates (n = 1442), 2026 records remained: 32 from PsychInfo, 1807 from EMBASE, 167 from MedLine, six from CINAHL, 13 from CENTRAL and one from the ACBS RCT database. The title and abstract of each article were screened. Articles were rejected during this initial screening if the reviewer could conclude that the study did not meet the inclusion criteria. This excluded a total of 1948 articles. 78 studies remained that were subject to a full text review.

In addition, five individuals responded to the ACBS email and suggested a total of 13 studies, six of which met inclusion criteria for this review (Bohlmeijer, Fledderus, Rokx, & Pieterse, 2011; England et al., 2012; Mojtabaie & Asghari, 2014; Rafiee, Sedrpoushan, & Abedi, 2013; Tamannaeifar, Gharraee, Birashk, & Habibi, 2014; Yadegari et al., 2014). No further studies were identified through manually searching journals or through manual reference list searches.

Seventy-three studies were excluded after the full text review for failing to meet eligibility criteria (reasons are given in Figure 1). Fifteen of the eighteen authors of included studies were contacted (three could not be contacted). Three replied and collectively suggested no additional studies that were not already included within this review. The electronic search was repeated from April 2016 to January 2017 to ensure additional publications were not missed during the review process. This revealed no additional studies. Therefore, 18 studies were included in the final

review. Figure 1 shows the PRISMA flow diagram which summarises the study selection process.

6.2 Study characteristics

Characteristics of each study are presented in Table 1. The 18 RCTs included a combined total of 983 participants. Across the trials, 77.1% of participants were female. The mean age was 34.9 years (range = 18 – 69). Eight studies compared ACT to an active treatment condition (five CBT, one relaxation training, one habituation-based exposure and one supportive group therapy). Eight studies compared ACT to a non-active comparison condition. Of these, three were classed as treatment as usual (Folke, 2012; Morton, 2012; Pankey & Hayes, 2008), two waiting-list controls (therapy offered after the intervention; Bohlheimer, 2011; Eilenberg, Fink, Jenson, Rief, & Frostholm, 2015) and three controls (no therapy offered; Mojabaie, 2014; Rafiee, 2013; Yadegari, 2014). Two studies compared ACT to both an active treatment (CBT) and a non-active treatment condition (Kocovski, Fleming, Hawley, Huta, & Antony, 2013; Lanza, 2014). All studies took place in Western societies, except for three studies which took place in Iran. Six studies were conducted in Europe, five studies were conducted in the USA, and four studies were conducted in Australia. Most interventions took place in a clinical setting (n = 12). Three took place in a University, two within public services and one unspecified. Fifteen studies were peer-reviewed journals and three studies were degree dissertations/theses (Pankey & Hayes, 2008; Pellowe, 2006; Renko & Deane, 2013). Groups ranged from 4-12 participants. The number of sessions ranged from 6-16, with a mean of 9.1 sessions (*SD* = 3.72). The mean number of hours per intervention was 16.5 (*SD* = 8.22). The primary target of intervention was the reduction of

psychological distress, with only four studies focusing on improving quality of life (Avdagic et al., 2014, Clarke, Kingston, James, Bolderston, & Remington, 2014, Eilenberg et al., 2015 & Folke et al., 2012). Most included studies focused on depression (n = 7) and anxiety disorders (generalized anxiety disorder [1], health anxiety disorder [1], social anxiety disorder [3], and non-specific clinical anxiety [2]) with only single studies focusing on personality disorder, substance use, treatment resistant conditions and a dual diagnosis of mixed mental health disorders with a learning disability. Three studies targeted anxiety/depression in the context of physical health conditions (multiple sclerosis, breast cancer and obesity).

All studies relied on subjective self-report outcome measures. The average attrition rate across studies from assessment to post-treatment was 17.22% (median = 13) and to follow-up was 22.11% (median = 17), with the ACT interventions having smaller attrition rates (post-treatment = 12.78%, median = 14; follow-up = 17.29%, median = 5.5), than the comparison groups (post-treatment = 21.08%, median = 23; follow-up = 22.15%, median = 16).

6.3 Risk of bias within studies

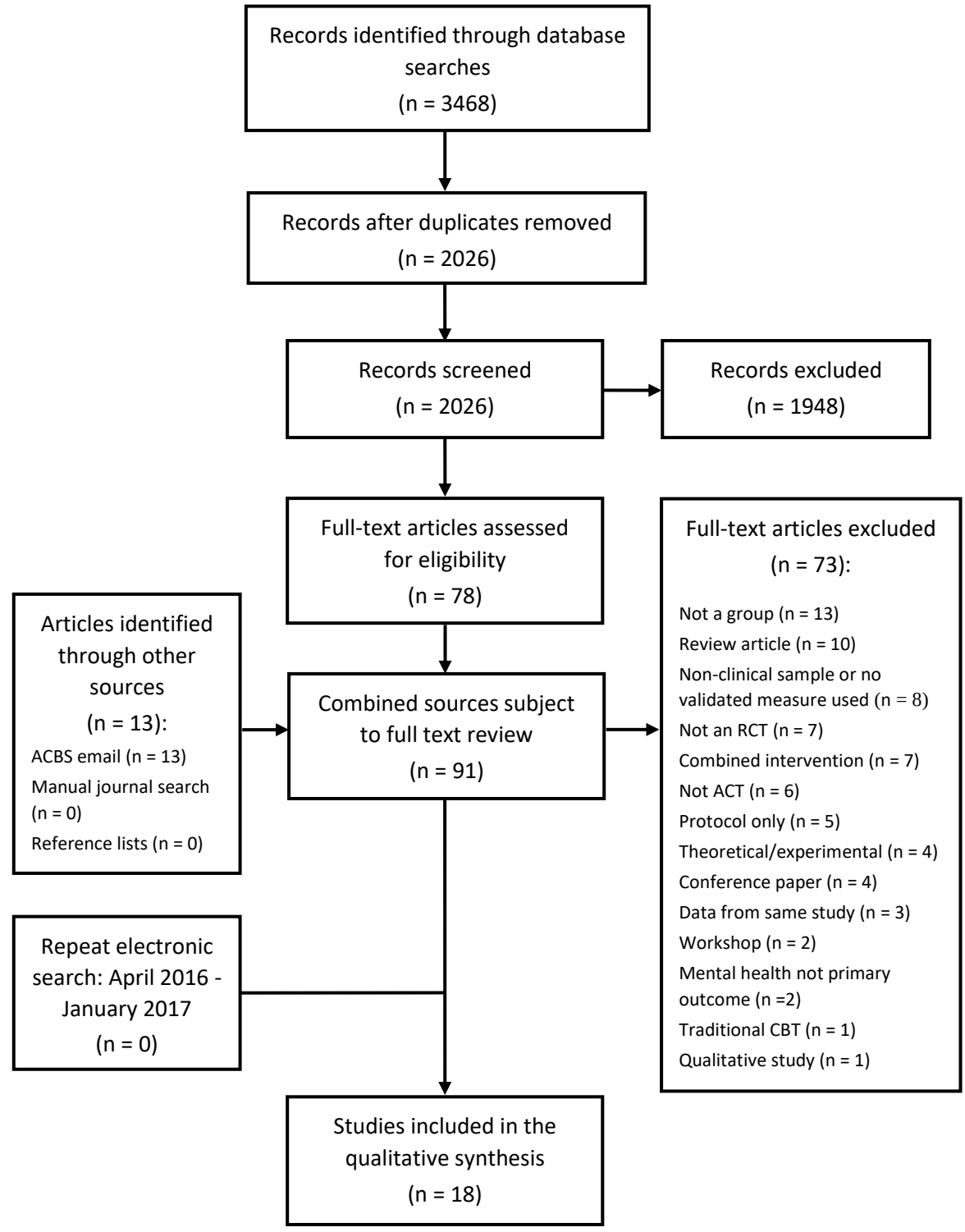
One review author (SF) independently extracted the data from each included study to assess risk of bias. The second author (SR) blind rated one third of the studies and Cohen's weighted kappa (κ) was calculated as an index of inter-rater reliability. This output showed that $\kappa = 0.85$, which is classed as a 'very good' strength of agreement between the raters, according to Altman (1991). Any disagreements were resolved through discussion and consensus.

The profile of quality review scores are outlined in Figure 2. Low risk of bias was assigned to studies that had no 'very likely risk of bias' scores across each domain, somewhat likely risk of bias was assigned to studies with one 'very likely risk of bias' score across the domains and very likely risk of bias was assigned when two or more 'very likely risk of bias' were scored across the domains.

Based on these criteria, three studies were assessed as having unlikely risk of bias (Bohlmeijer et al., 2011; Eilenberg, 2015; Pankey & Hayes, 2008), ten studies were assessed as having somewhat risk of bias (Avdajic et al., 2014; Clarke et al., 2014; England et al., 2012; Folke et al., 2012; Lanza et al., 2014; Mojtabaie & Asghari, 2014; Morton et al., 2012; Nordin & Rorsman, 2012; Renko & Deane, 2013; Zettle & Rains, 1989), and five studies were assessed as having a likely risk of bias (Kocovski et al., 2013; Pellowe 2006; Rafiee et al., 2013; Tamannaeifar et al., 2014; Yadegari et al., 2014).

All studies used appropriate data collection methods and reported appropriate study designs. All studies used statistical methods appropriate for the study design and most studies adopted an intention to treat analysis. However, power calculations were not reported or sufficient power was not achieved in many of the studies.

Thirteen studies (72%) commented on treatment fidelity: seven studies (38%) reported the use of recordings or videos of sessions to rate adherence to the therapy model. Six studies (33%) reported using adherence scores. Of these, all studies reported acceptable adherence to the model in question. In six of the nine studies (67%) containing an active control comparison, the same therapist(s) provided the intervention for both groups.



ACBS – Association of Contextual Behavioral Science

Figure 1: PRISMA flow diagram of systematic study selection process

The overall average attrition at post-treatment was 13.5% (range: 0 – 57%) and at follow-up was 24.5% (range: 0 – 60%). The average attrition for the ACT groups was 13.9% (range: 0 – 57%) at post-treatment and 25.9% (range: 0 – 56%) at follow-up. The average attrition for the active controls was 15.5% (range: 0 – 54%) at post-treatment and 27.75% (range: 0 – 60%) at follow-up. The average attrition for the non-active control was 10.82% (range: 0 – 35%) at post-treatment and 11.0% (range: 0 – 35%) at follow-up.

Eleven out of the eighteen of studies reported on the experience and supervision of facilitators to some extent. Most studies did not use double blinding methods, with four studies (Clarke, 2014; Lanza, 2014; Nordin, 2011; Pellowe, 2006) reporting no blinding methods at all. No studies achieved ‘not likely risk’ for selection bias, with six studies scored as having ‘very likely risk’ of selection bias due to the sample being self-referred (Avdagic, 2004; England, 2012; Kocovski, 2013; Pellowe, 2006; Zettle & Rains, 1989) or more than 40% of those initially eligible not taking part (Folke, 2012).

Table 1
Characteristics of included review studies

Authors (year) *Country*	Design *Analysis*	Modified EPHPP score for risk of bias	Mental health disorder	Gender (% female) Total sample *OR ACT/ Comparison*	Mean age (years) at baseline (SD) Total sample *OR* ACT/Comparison	Groups	Sample size	Primary target of intervention	Format of intervention/ *n per group*	No of sessions /total hours	Follow-up (months)	Outcome measures *Primary outcome measure(s) in italics*	Key finding(s)
Avdagic *et al.* (2014) *Australia*	RCT *ANOVA (ITT analysis)*	Somewhat likely	Generalised Anxiety Disorder (GAD)	*72/ 57.7*	36.17 (13.1)	ACT CBT	51	Treatment of distress & improving quality of life	Group *4-6*	6/12	3	*ADIS-IV* *PSWQ* *DASS-21* QOLI AAQ-9 Willingness Action IUS CAQ WW-II	Significant improvements on all measures for both treatment conditions. Treatment gains were maintained at follow-up. Equivalent changes between groups at follow-up. The ACT group was as efficacious as group CBT.
Bohlmeijer *et al.* (2011) *The Netherlands*	RCT *ANCOVA (ITT analysis)*	Not likely	Mild-to-moderate depression	*85.7/ 77.3*	*48.84/ 49.23*	ACT Waitlist	93	Improving mental, emotional, social and psychological wellbeing	Group *Average of 7*	8/16	5	*CES-D* HADS-A CIS AAQ-II	At posttreatment, CBT was more effective than ACT in reducing anxiety sensitivity; however, at follow-up, ACT was more effective than CBT in reducing drug use and improving mental health.
Clarke *et al.* (2014) *United Kingdom*	RCT *Mixed design ANOVAs, Fisher's Exact Test, Multiple regressions.*	Somewhat likely	Treatment resistant individuals	*73.3/ 61.3*	*44.03/ 42.90*	ACT CBT	61	Treatment of distress & improving quality of life	Group *Max. 11*	16/32	6	*SCL-90-R* *GSI* *BDI-II* SCID-II WHOQOL AAQ MAAS ATQ/TB ATQ/TF DUACRS	Substantial improvements for a heterogeneous group of treatment-resistant participants. Improvements were more completely sustained in the ACT group at 6-month follow-up.
Eilenberg *et al.* (2015) *Denmark*	RCT *Fitted five mixed models with random intercept and a cluster effect for treatment group.*	Not likely	Health anxiety	*73/ 68*	*37/ 35.5*	ACT Waitlist	126	Treatment of distress & improving quality of life	Group *9*	10/30	10	*WI (7-item version)* SCL-8 SCL-som SF-36 (PCS) SF-36 (MCS)	Statistically significant mean difference on the WI between the groups at 10 months, and the between-group effect sizes were large in favour of ACT.

Cont…

Authors (year) *Country*	Design *Analysis*	Modified EPHPP score for risk of bias	Mental health disorder	Gender (% female) Total sample *OR ACT/ Comparison*	Mean age (years) at baseline (S.D.) Total sample *OR* ACT/Comparison	Groups	Sample size	Primary target of intervention	Format of intervention/ *n per group*	No of sessions /total hours	Follow-up (months)	Outcome measures *Primary outcome measure(s) in italics*	Key finding(s)
England *et al.* (2012) *U.S.A*	RCT *ANOVAs*	Somewhat likely	Public speaking anxiety (diagnosed as social anxiety disorder)	80	31.93		ABE HBE	45	Group *4-8*	6/12	1.5	PRCS SSPS + SPSS - STAI CGI Severity DDS PHLMS Accept Aware	Participants receiving acceptance-based exposure (ABE) were significantly more likely than those receiving habituation-based exposure (HAB) to achieve diagnostic remission by 6-week follow-up.
Folke *et al.* (2012) *Sweden*	RCT *Mixed Model Repeated Measures (MMRM)*	Somewhat likely	Unipolar Depressive Disorder	*94.4/ 81.3*	*40.5/4 6.25*	ACT Control (TAU)	35	To increase quality of life and prevent prolonged long-term sick leave	Group *Not reported*	6/11-16.5	18	*BDI* *GHQ-12* WHOQOL-BREF	ACT participants significantly improved from pre-treatment to follow-up on measures of depression, general health and quality of life, compared to the control condition.
Kocovski (2013) *Australia*	RCT *Hierarchical Linear Model (HLM) & ANOVA*	Very likely	Social Anxiety Disorder	*52.83/ 49.06/ 64.52 (WL)*	*32.66/ 34.94/ 36.55* (WL)	CBGT MAGT Waitlist	137	Treatment of distress	Group *Not reported*	12/24	3	*SPIN* FMI SA-AAQ ERQ RRQ LSAS CGI BDI VLQ GCS-R	CBGT and MAGT were both more effective than the control group but not significantly different from one another on social anxiety reduction.
Lanza *et al.* (2014) *Spain*	RCT *ANOVAs*	Somewhat likely	Substance Use Disorder	100	*31.1/ 35.2/ 33.1* (Control)	ACT CBT Control	50	Treatment of distress	Group *Not reported*	16/24	6	ASI-6 MINI ASI AAQ-II UM SR	CBT was more effective than ACT in reducing anxiety sensitivity; however, at follow-up, ACT was more effective than CBT in reducing drug use and improving mental health.
Mojtabaie and Asghari (2014) *Iran*	RCT *ANCOVA*	Somewhat likely	Depression	100	*Not specified*	ACT Control	30	Treatment of distress	Group *Not reported*	8/8	0	*BDI-II*	Depression scores significantly decreased in the ACT group compared to control.
Morton *et al.* (2012) *Australia*	RCT *Mixed model, repeated measures*	Somewhat likely	Borderline Personality Disorder	*90.5/ 95*	*35.6/ 34.0*	ACT Control (TAU)	41	To create positive change on anxiety, hopelessness	Group *4-6*	12/24	3 *(for ACT group only)*	*BEST* DASS Stress Anxiety Depression	ACT and TAU had significantly more positive change on anxiety, hopelessness, psychological flexibility, emotion regulation skills, mindfulness and fear of emotions.

Cont…

Authors (year) *Country*	Design *Analysis*	Modified EPHPP score for risk of bias	Mental health disorder	Gender (% female) Total sample *OR ACT/ Comparison*	Mean age (years) at baseline (S.D.) Total sample *OR* ACT/Comparison	Groups	Sample size	Primary target of intervention	Format of intervention/ *n per group*	No of sessions /total hours	Follow-up (months)	Outcome measures *Primary outcome measure(s) in italics*	Key finding(s)
	ANOVAs, Reliable change indexes.							psychological flexibility, emotion regulation skills mindfulness and fear of emotions.				BHS AAQ FFMQ ACS DERS	
Nordin and Rorsman (2012) *Sweden*	RCT *Mann-Whitney U tests and χ2 analyses*	Somewhat likely	Anxiety & Depression	*80/ 80*	*43/ 48.5*	ACT Relaxation Training	21	Treatment of psychological distress within MS sufferers	Group *Not reported*	5/-	3	HADS-A HADS-D BDI AAQ	Similar reductions in anxiety and depression between groups at follow-up.
Pankey and Hayes (2009) *U.S.A.*	RCT *Repeated measures analysis of covariance (RMANCOVA)*	Not likely	Mild to moderate mental retardation and co-morbid diagnosis of Axis I disorder.	*58.3/ 45.5*	*29.17/ 27.91*	ACT Control (TAU)	23	Treatment of psychological distress	Group *6*	4/6	1	ADAMS VABS GASPID ZSRDS LS AFQ-Y BE ATQ	Brief group ACT for cognitively disabled individuals improved functioning, reduced psychopathology, increased psychological flexibility, and increased time spent focused on the importance of values and living in line with one's values.
Pellowe (2006) *U.S.A.*	RCT *Paired samples t-test*	Very likely	Dysphoria	*76/ 63*	*28.84/ 20.07*	ACT SGT	52	Treatment of psychological distress	Group *2-10*	4/3.5	0	*AAQ* *BDI-II* DAS	The ACT group reported significant increases in psychological flexibility compared to supportive therapy. The ACT group had a higher frequency of depression-related cognitions and attitudes and decreases in depressive symptoms.
Rafiee *et al.* (2013) *Iran*	RCT *ANOVA/ Fisher's LSD*	Very likely	Depression	100	*Range*: 25-45	ACT Control	34	Treatment of psychological distress	Group *Not reported*	8/16	1	*BDI* FBIT	ACT decreases depression and body image dissatisfaction
Renko and Deane (2013) *Australia*	RCT *ANOVA / ITT*	Somewhat likely	Mild-to-severe levels of anxiety	56.8	26.5	ACT CBT	118	Treatment of distress	Group *8-12*	6/12	3 & 6	BAI SCL-90 R BAFT MAAS AAQ	ACT is a highly viable treatment for anxiety and is just as effective as CBT.

Cont…

Authors (year) *Country*	Design *Analysis*	Modified EPHPP score for risk of bias	Mental health disorder	Gender (% female) Total sample *OR ACT/ Comparison*	Mean age (years) at baseline (S.D.) Total sample *OR* ACT/Comparison	Groups	Sample size	Primary target of intervention	Format of intervention/ *n per group*	No of sessions /total hours	Follow-up (months)	Outcome measures *Primary outcome measure(s) in italics*	Key finding(s)
												Willingness subscale Action subscale	
Tamannaeifar *et al.* (2014)	RCT *MANCOVA*	Very likely	Depression	100	*24.7/ 25.7*	ACT CBT	19	Treatment of psychological distress	Group *Not reported*	12/-	0	SCID-IV BDI-II RRS	ACT is as effective a treatment in reducing depression compared to CT
Yadegari *et al.* (2014) *Iran*	RCT *ANCOVA*	Very likely	Social anxiety	*38/ 62*	*22.38/ 23.5*	ACT Control	16	Treatment of psychological distress	Group *8*	12/-	0	SPAI	12 sessions of ACT could significantly reduce the symptoms of social anxiety among the participants in the experimental group.
Zettle and Rains (1989) *U.S.A.*	RCT *ANCOVA*	Somewhat likely	Depression	100	41.3	CCT PCT CD	31*	Treatment of psychological distress	Group *4-7*	12/18	2	BDI MMPI HRSD ATQ DAS PES	Significant and equivalent reductions in depression were found across the three groups.

*Six subjects dropped out during treatment but the condition and at what point are not specified

EPHPP – Effective Public Health Practice Project; HBE–Habituation-based exposure; SGT–Supportive group therapy; TAU–Treatment as usual.
Measures: AAQ-II–Acceptance and Action Questionnaire-II; ACS–Affective Control Scale; ADAMS–The Anxiety, Depression and Mood Scale; ADIS-IV–Anxiety Diagnostic Interview Schedule; AFQ-Y–The Avoidance and Fusion Questionnaire for Youth; ASI–Anxiety Sensitivity Index; ASI-6–Addiction Severity Index; ATQ–The Automatic Thoughts Questionnaire; BAFT–Believability of Anxious Feelings and Thoughts; BAI–Beck Anxiety Inventory; BDI-II–Beck Depression Inventory-II; BE–Bull's Eye measure; BEST–Borderline Evaluation of Severity over Time; BHS–Beck Hopelessness Scale; CAQ–Cognitive Avoidance Questionnaire; CES-D–Center for Epidemiologic Studies Depression Scale; CIS–Checklist Individual Strength; CGI–Clinical Global Impression Scale; DAS-Dysfunctional Attitude Scale; DASS–Depression, Anxiety and Stress Scale; DERS–Difficulties in Emotion Regulation Scale; DDS–Drexel Defusion Scale; DUTACRS-Drexel University therapist adherence and competence rating scale; ERQ–Emotion Regulation Questionnaire; FBIT-Fisher's Body Image Test; FFMQ–Five Facet Mindfulness Questionnaire; FMI–Freiburg Mindfulness Inventory; GASPID–The Glasgow Anxiety Scale for People with Intellectual Disabilities; GCS-R–Group Cohesion Scale-Revised; GHQ-12–General Health Questionnaire; HADS-A–Hospital Anxiety and Depression Scale–Anxiety Subscale; HRSD–Hamilton Rating Scale for Depression; IUS–Intolerance of Uncertainty; LS–Life Scale (investigator authored); LSAS–Liebowitz Social Anxiety Scale; MAAS–Mindful Attention and Action Questionnaire; MINI–Mini International Neuropsychiatric Interview; MMPI–Minnesota Multiphasic Personality Inventory; PES–Pleasant Events Scale; PHLMS–Philadelphia Mindfulness Scale; PRCS–Personal Report of Confidence as a Speaker; PSS–Perceived Stress Scale; PSWQ–Penn State Worry Questionnaire; QOLI–Quality of Life Inventory; RRQ–Rumination Reflection Questionnaire; RRS–Ruminative Response Scale; SA-AAQ–Social Anxiety Acceptance and Action Questionnaire; SCID-II–Structured Clinical Interview for DSM-IV Axis II Disorders; SCL-8–Symptom Checklist Scale; SCL-90-R–Symptom Checklist-90 Revised; SCL-som–Symptom Checklist Scale, Somatization Subscale; SF-36 (PCS & MCS)–Short-Form Health Survey, Physical Component Summary & Mental Component Summary; SPAI–Social Phobia and Anxiety Inventory; SPIN–Social Phobia Inventory; SR–Self-recording; SSPS–Self-Statements During Public Speaking; STAI–State-Trait Anxiety Inventory; TBTF–Thought Believability and Frequency; UM–Urinalysis Multidrug; VABS–The Vineland Adaptive Behavior Scales; VLQ–Valued Living Questionnaire; WW-II–Why Worry-II; WHOQOL–World Health Organisation Quality of Life Questionnaire; WHOQOL-BREF–World Health Organisation Quality of Life assessment; WI–Whiteley-7 Index; ZSRDS–The Zung Self Rating Depression Scale.

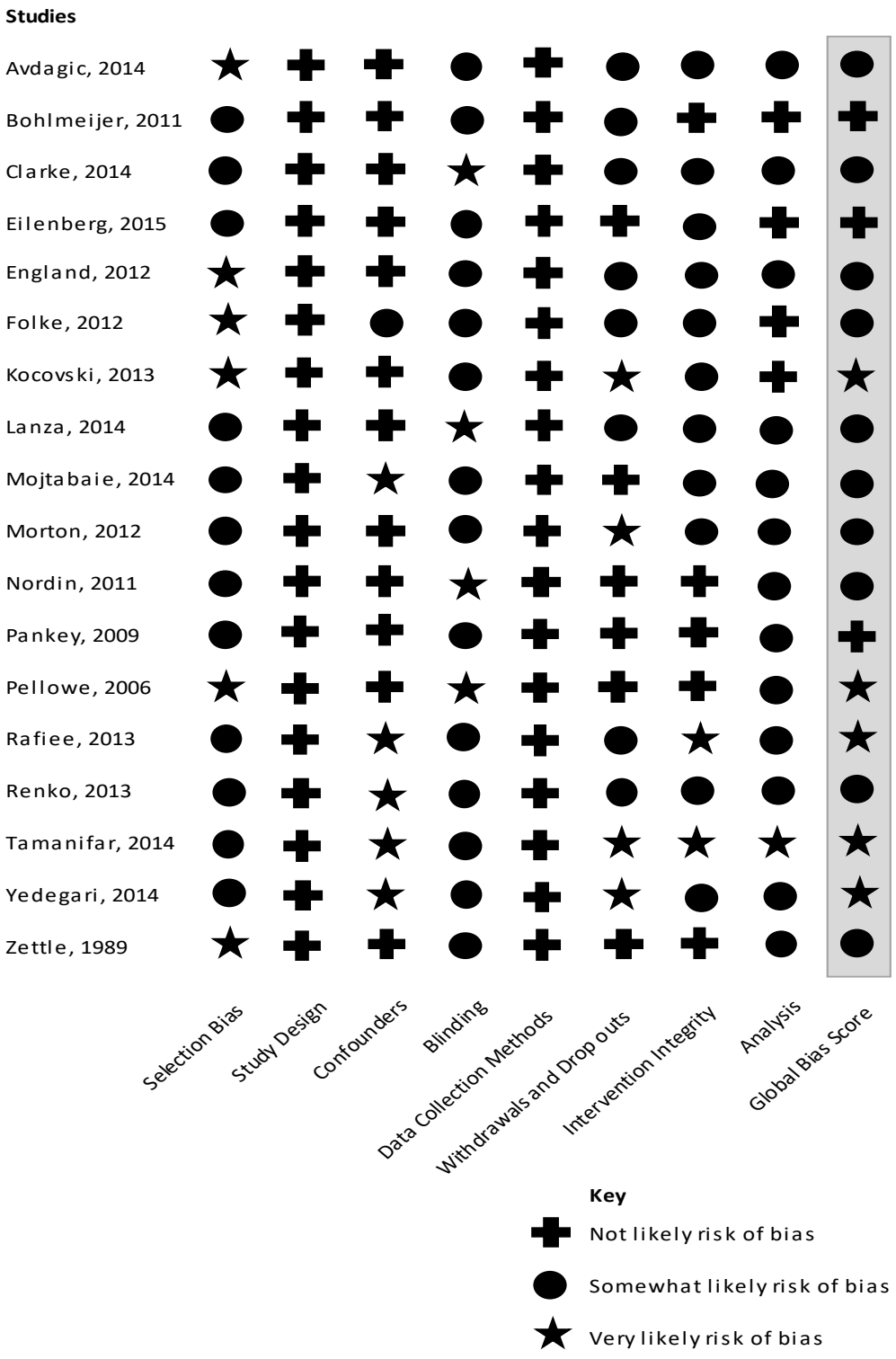


Figure 2. Risk of bias scores for the eighteen studies included in the review

6.4 Results of individual studies

Sample sizes, means, standard deviations, and effect sizes for each primary outcome measure are presented in Table 2. Effect sizes from the data extraction tables were converted to Hedge's *g* to correct for the small overestimation bias that using Cohen's *d* creates in small samples. Where effect sizes were not available, these were calculated using the available data. The data from Nordin and Rorsman (2012) reported inter-quartile ranges. For effect size calculations, these were entered as means with an approximate standard deviation of 1.35, as recommended in the Cochrane guidelines (http://handbook.cochrane.org/chapter_7/7_7_3_5_mediansand_interquartile_ranges.htm; under the assumption that the data is normally distributed).

6.5 Synthesis of results

A random-effects model was used to distinguish true heterogeneity in prevalence (due to differences in measurement, sample type and analysis conducted) from sampling error. Hedges' *g* was calculated with a 95% confidence interval. Cohen's (1988) constructs of small (0.2), medium (0.5) and large (0.8) were adopted to interpret Hedges' *g* effect sizes. MetaXL allowed for the input of a quality rank derived from a univariate quality score. Risk of bias ratings of 'very likely', 'somewhat likely' and 'not likely' were numerically scaled as quality ranks to be included within the analysis. MetaXL redistributes assigned weights based on the quality scores which helps reduce estimator variance. It calculates between study bias variance divided by the sum of within and between study variance (Barendregt & Doi, 2011).

The Q statistic represents the ratio of observed variation to the within-study error (Borenstein, Hedges, Higgins, & Rothstein, 2009). It relies on the number of studies within the meta-analysis and can have low power when the number of studies are small (Gavaghan, Moore, & McQay, 2000) or too much power when the number of studies are large (Higgins, Thompson, Deeks, & Altman, 2003). However, it allows a probability value, thus can serve as a test of significance. The I^2 statistic is a percentage of variation across studies due to heterogeneity rather than chance (Higgins & Thompson, 2002). It does not rely on number of studies nor the metric of the effect size. Higgins et al., (2003) proposed benchmarks for this measure of 25%, 50% and 75% translated as low, moderate and high heterogeneity, respectively. Both statistics were incorporated into each meta-analysis to identify variations within studies.

Table 2. Sample sizes, means, standard deviations and effect sizes for the primary outcomes of studies (ordered by study quality).

Author (year)	Primary outcome measure(s)	Condition	Sample size (initial/ completed/ follow-up)	Mean (SD) pre	Mean (SD) post	Mean (SD) follow-up	Within group effect sizes (*d*; ACT), pre-post/pre-follow-up	Between group effect sizes (*g*)• at post and CI	Between group effect sizes (*g*) • at follow-up and CI
Bohlmeijer *et al.* (2011)	CES-D	ACT	49/39/36	23.94 (9.91)	15.94 (10.37)	14.78 (9.49)	0.86 / 1.03	-0.60	-0.62
		Waitlist	44/42/41	26.11 (9.12)	22.07 (9.99)	21.17 (10.71)		(-1.04, -0.15)	(-1.08, -0.16)
Eilenberg *et al.* (2015)	WI	ACT	63/54/52	56.9 (19.69)	-	34.8 (23.29)	- / 2.57	-	-0.85
		Waitlist	63/59/55	57.7 (25.53)	-	56.10 (26.13)		-	(-1.25, -0.46)
Pankey and Hayes (2009)	ADAMS	ACT	12/12/12	48.92 (10.96)	41.87 (10.96)	40.00 (10.33)	0.67 / 1.35	-0.75	- 0.89
		Control	11/11/11	48.00 (13.76)	51.49 (13.76)	51.18 (13.82)		(-1.60, 0.10)	(-1.75, -0.02)
Nordin and Rorsman (2012)	BDI	ACT	11/10/10	13 (1.35)	12 (1.35)	10 (1.35)	- / -	-1.06	-0.71
		RT	10/10/10	15 (1.35)	13.5 (1.35)	11 (1.35)		(-2.01, -0.11)	(-1.62, 0.20)
Zettle and Rains (1989)	BDI	CD	11/11/11*	29.27 (6.16)	11. 27 (7.39)	6.09 (4.09)	1.91 / 3.25	-0.51	-0.62
		CCT	10/10/10	26.90 (5.42)	16.2 (10.83)	12.90 (12.21)		(-1.40, 0.38)	(-1.72, 0.49)
		PCT	10/10/10	26.20 (3.91)	12.40 (7.60)	7.00 (7.50)			
Avdagic *et al.* (2014)	PSWQ	ACT	25/19/15	67.7 (8.5)	50.95 (10.5)	52.20 (12.3)	4.41 / 3.72	-0.60	-0.02
		CBT	26/19/15	66.6 (8.3)	57.37 (10.3)	52.47 (14.5)		(-1.26, 0.05)	(-0.74, 0.70)
Clarke *et al.* (2014)	BDI-II	ACT	30/26/25	29.58 (9.58)	14.58 (12.99)	14.29 (11.69)	3.35 / 3.84	-0.16	-0.46
		CBT	31/19/17	25.20 (13.77)	16.66 (11.57)	20.60 (15.89)		(-0.76, 0.43)	(-1.08, 0.17)
England *et al.* (2012)	PRCS	ABE	21/16/16	2.33 (1.65)	6.33 (3.20)	6.75 (2.94)	2.48 / 2.90	-0.34	-0.01
		HBE	24/19/19	2.58 (1.38)	7.42 (3.05)	6.87 (3.29)		(-1.01, 0.33)	(-0.67 – 0.66)
Folke *et al.* (2012)	BDI	ACT	18/14/13	21.11 (10.94)	15.43 (9.61)	15.21 (9.28)	1.38 / 1.45	-0.66	-0.46
		Waitlist	17/11/11	22.38 (11.41)	22.45 (11.13)	20.46 (12.61)		(-1.47, 0.16)	(-1.28, 0.35)

Cont…

Author (year)	Primary outcome measure(s)	Condition	Sample size (initial/ completed/ follow-up)	Mean (SD) pre	Mean (SD) post	Mean (SD) follow-up	Within group effect sizes (ACT group)	Between group effect sizes• at post and CI	Between group effect sizes• at follow-up and CI
Lanza *et al.* (2014)	ASI	ACT	18/18/14	21.1 (14.7)	21.1 (14.8)	18.8 (14.6)	0.00 / 0.20	ACT vs CBT: 0.22 (-0.58, 1.01)	-0.13 (-1.02, 0.76)
		CBT	19/19/16	31.2 (17.4)	18 (13.6)	21.03 (20.1)			
		Control	13/13/11	23.3 (15.3)	27.4 (11.1)	25.7 (15.9)		ACT vs Control: -0.48 (-1.34, 0.39)	-0.43 (-1.39, 0.53)
Mojtabaie and Asghari (2014)	BDI-II	ACT	15/15	24.73 (3.17)	15.07 (2.65)	-	4.28 / -	-2.74	-
		Control	15/15	25.93 (1.94)	22.53 (2.64)	-		(-3.78, -1.71)	-
Morton *et al.* (2012)	BEST	ACT	21/18/10	44.57 (11.16)	32.76 (12.47)	30.60 (11.95)**	1.14 / 1.38	-1.21	-
		Control	20/14/-	49.80 (12.35)	47.42 (11)	-		(-1.97, -0.44)	-
Renko and Deane (2013)	BAI	ACT	61/26/27	16.56 (11.48)	11.94 (9.14)	9.37 (15.48)	0.63 / 0.75	0.00	-0.09
		CBT	57/26/23	16.78 (11.09)	11.97 (8.94)	10.7 (14.67)		(-0.55, 0.54)	(-0.64, 0.47)
Pellowe (2006)	BDI-II	ACT	25/22	12.16 (7.26)	7.16 (5.23)	-	2.14 / -	-0.62	-
		Control	27/19	15.44 (7.28)	11.89 (9.52)	-		(-1.25, 0.01)	-
Kocovski (2013)	SPIN	MAGT	53/37/32	42.43 (12.84)	33.91 (14.79)	29.40 (13.72)	1.31 / 2.09	MAGT vs CBGT: 0.01 (-0.56, 0.59)	0.31 (-0.21 – 0.82)
		CBGT	53/32/27	43.68 (12.16)	33.72 (14.04)	25.33 (12.11)			
		Waitlist	31/31	46.71 (8.92)	43.82 (9.90)	-		MAGT vs Waitlist: -0.81 (-1.41, -0.22)	-
Rafiee *et al.* (2013)	BDI	ACT	17/15	23.8 (3.91)	20.2 (3.4)	20.47 (4.2)	2.63 / 2.19	-0.85	-0.57
		Control	17/15	23 (2.45)	22.67 (2.12)	22.4 (2.06)		(-1.60, -0.10)	(-1.30, 0.16)
Yadegari *et al.* (2014)	SPAI	ACT	8/8	134.62 (40.44)	57. 87 (22.04)	-	4.81 / -	-2.18	-
		Control	8/8	148 (52.01)	149.5 (51.74)	-		(-3.49, -0.87)	-
Tamannaeifar *et al.* (2014)	BDI	ACT	10/10	33.3 (11.25)	28.2 (16.28)	-	0.99 / -	0.72	-
		CT	10/9	28.4 (7.74)	18.5 (7.65)	-		(-0.22, 1.65)	-

Measures: ADAMS–Anxiety, Depression & Mood Scale, ASI–Addiction Severity Index, BAI–Beck Anxiety Inventory, BEST–Borderline Evaluation of Severity Over Time, BDI–Beck Depression Inventory, CD–Comprehensive Distancing, CES-D-Center for Epidemiologic Studies Depression Scale, PRCS–Personal Report of Confidence as Speaker, PSWQ-Penn State Worry Questionnaire, SPAI–Social Phobia and Anxiety Inventory, SPIN–Social Phobia Inventory, WI–Worry Inventory.
CBGT – Cognitive Behavioural Group Therapy, CCT-Complete Cognitive Therapy, MAGT – Mindfulness and Acceptance-based Group Therapy, PCT–Partial Cognitive Therapy, RT – Relaxation Training.
*Six subjects dropped out during treatment but the condition and at what point are not specified, ** ACT group outcomes at follow-up only, • a minus sign indicates 'favouring ACT'

6.6 Within-group effect sizes

To highlight the efficacy of ACT as a group intervention for the treatment of mental health disorders, within-group effect sizes using pre-post data from the ACT arm of each study were calculated. Only six studies reported within-group effect sizes. The remaining authors were contacted to request the correlation between the two means which is needed to correct for dependence among means (Morris & DeShon, 2002). Only two authors responded; one of which could not provide the correlation as they no longer had access to the data. Therefore, within-group effect sizes were calculated with an estimated correlation taken from the test-retest reliability scores of the outcome measure in question. This produced an average effect size of d = 2.06 at post-treatment (range = 0.00 – 4.81) and an average effect size of d = 2.05 at follow-up (range = 0.20 – 0.38).

6.7 Analysis of between-group outcomes at post-treatment

Studies were separated into active and non-active treatment controls and compared to ACT-based group interventions at post-treatment. Studies which used multiple intervention comparisons (Kocovski et al., 2013; Lanza et al., 2014) were split into two pair-wise comparisons with the total number of patients in the shared intervention divided evenly among the two comparisons. This allowed the partial avoidance of unit-of-analysis error (due to the unaddressed correlation between the estimated intervention effects from multiple comparisons; Higgins et al., 2008). Supportive group therapy (Pellow, 2006) was deemed to be an active control group, whereas treatment as usual, unless described sufficiently to be clear that it was an active treatment, was allocated to the non-active control comparison. For the study

which utilised both control and active treatments (Kocovski, 2013) the respective conditions were used in each separate meta-analysis. The study by Zettle and Rains (1989) utilised a third comparison intervention in addition to ACT compared to cognitive therapy. This was labelled 'partial cognitive therapy' and excluded 'distancing' from the traditional cognitive therapy intervention. This was for theoretical reasons as opposed to a third distinct therapy and was therefore not included in this analysis.

In the pooled analysis, an effect size of -0.25 (CI = -0.52 - 0.02) favouring ACT was found compared to active treatment controls. A non-significant heterogeneity within this comparison was identified (Q = 12.67; p = 0.18; I^2 = 29%) with effect sizes ranging from -1.06 to 0.72.

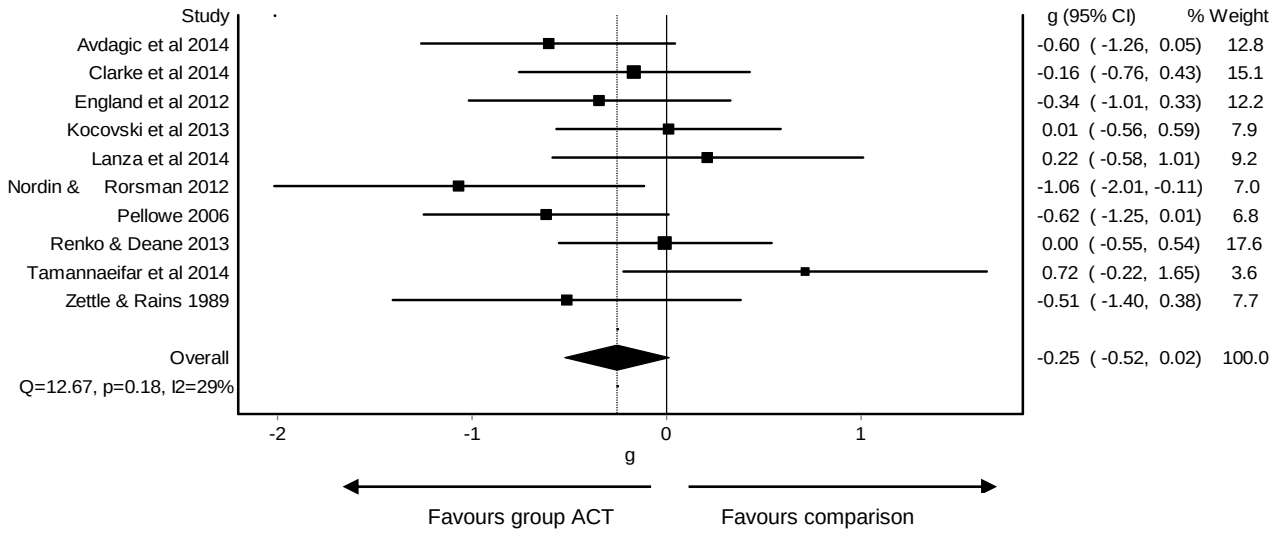


Figure 3. Forest plot for overall active post-treatment effect sizes

An effect size of -0.91 (CI = -1.37 - -0.44) favouring ACT was found compared to non-active treatment controls. A significant heterogeneity within this comparison

was identified (Q = 19.76; p = 0.01; I^2 = 60%). Effect sizes ranged from -2.74 to -0.48, indicating no studies favoured the control group.

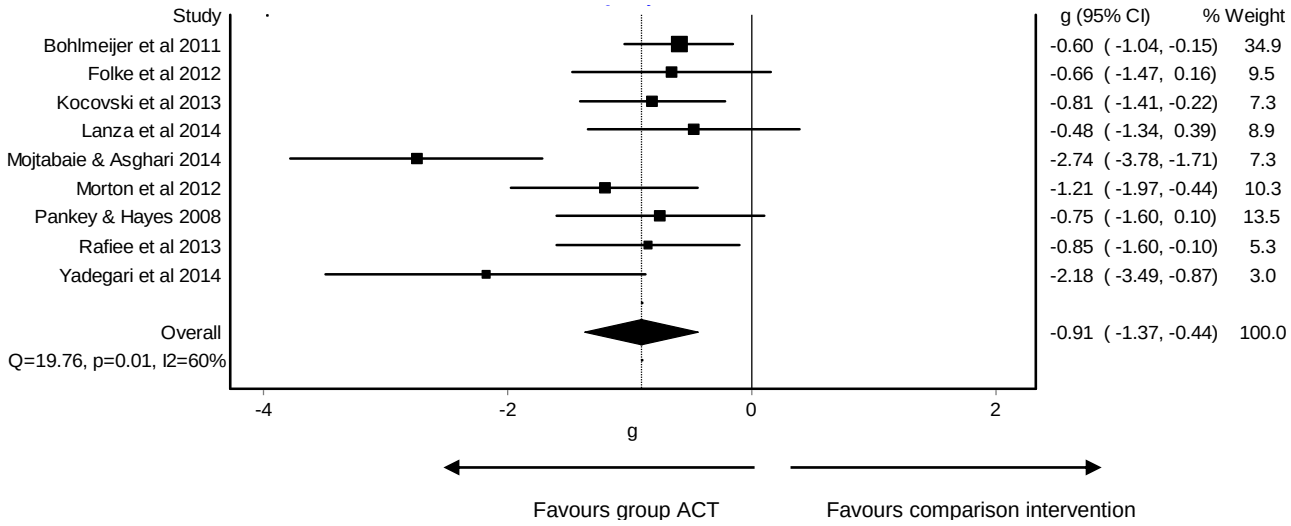


Figure 4. Forest plot for overall non-active post-treatment effect sizes

6.8 Anxiety and depression at post-treatment

Fourteen studies looking at participants with anxiety and depression were analysed separately. Four studies with complex samples were not able to be analysed as Clarke et al., (2014) used an active control group, whereas the remaining three studies used non-active controls, meaning there were too few studies to provide meaningful analysis.

6.8.1 Subgroup analysis of between-group outcomes for active treatment controls

In the pooled analysis of between group effect sizes for ACT groups vs active treatment controls a small-to-moderate overall effect size of -0.33 (CI = -0.66 – 0.00) favouring ACT was found. A non-significant heterogeneity within this comparison

was identified (Q = 11.27; p = 0.13; I^2 = 38%). Two outliers (Nordin & Rorsman, 2012, ES = -1.06, CI = -2.01, -0.11; Tamannaeifar et al., 2014, ES = 0.72, CI = -0.22, 1.65) were identified. A sensitivity analysis was undertaken to exclude the two outliers. This reduced heterogeneity (Q = 4.31; p = 0.51; I^2 = 0%) suggesting the two studies were examining substantially different effects. Excluding these two studies adjusted the effect size to -0.31 (CI -0.58 – -0.04).

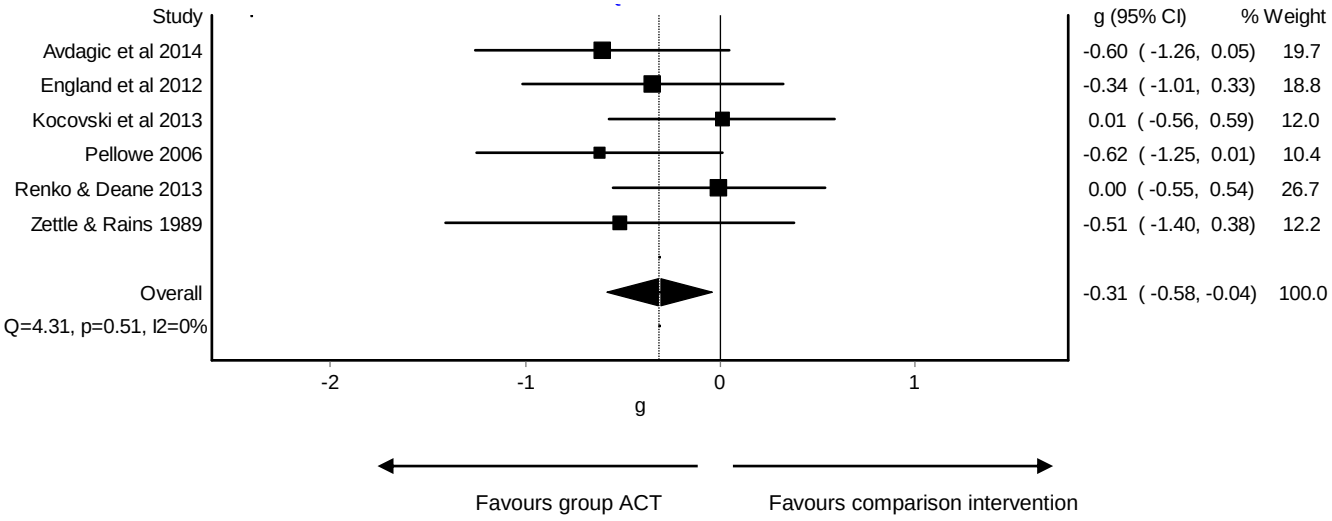


Figure 5. Forest plot for active post-treatment subgroup analysis of anxiety and depression

6.8.2 Subgroup analysis of between-group outcomes for non-active treatment controls

In the pooled analysis of between group effect sizes for ACT groups vs non-active controls a large overall effect size of -0.98 (CI = -1.69 – -0.26) favouring ACT was found. Data from Eilenberg (2015) was not included in this analysis as only data from 10-month follow-up was available. A significant heterogeneity within this comparison was identified (Q = 18.09; p = 0.00; I^2 = 72%). Two outliers (Mojtabaie & Asghari, 2014, ES = -2.74, CI = -3.78, -1.71; Yadegari, 2014, ES = 2.18, CI = -

3.49, -0.87) were identified. A sensitivity analysis was undertaken by excluding the two outliers. This significantly reduced the heterogeneity (Q = 0.51; p = 0.92; I^2 = 0%) indicating that the variability in effect sizes was due to sampling error. This gave a moderate effect size of -0.66 (CI = -0.98, -0.34).

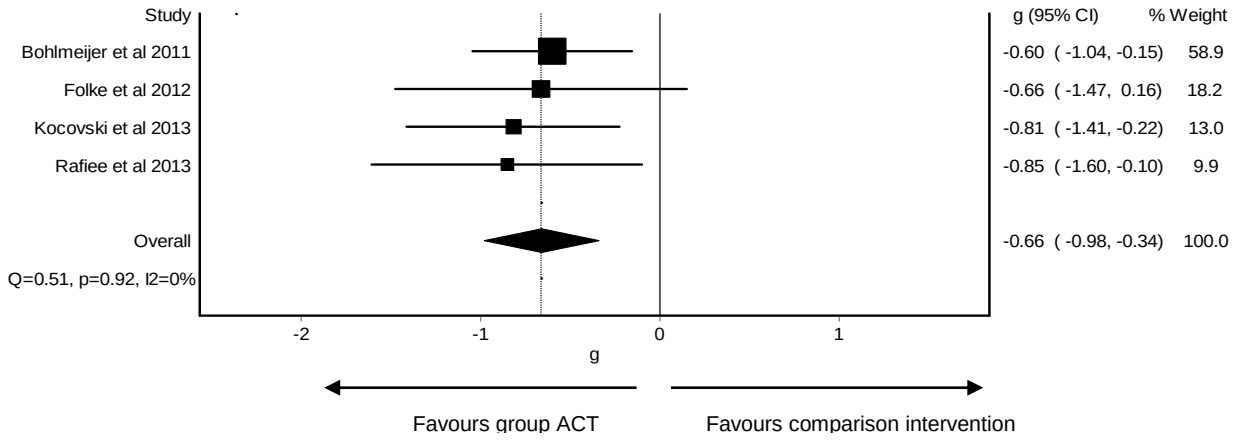


Figure 6. Forest plot for non-active post-treatment subgroup analysis of anxiety and depression

6.8.3 Subgroup analysis of between-group outcomes at follow-up

An analysis was run to investigate between group outcomes across ACT group versus comparison groups at follow-up. In the pooled analysis, an effect size of -0.18 (CI = -0.44 - 0.08) favouring ACT was found compared to active treatment controls. A non-significant heterogeneity within this comparison was identified (Q = 6.36; p = 0.50; I^2 = 0%) with effect sizes ranging from -0.44 to 0.08. In the pooled analysis, an effect size of -0.63 (CI = -0.90 - 0.35) favouring ACT was found compared to non-active treatment controls. A non-significant heterogeneity within this comparison was identified (Q = 1.62; p = 0.90; I^2 = 0%) with effect sizes ranging from -0.89 to -0.43.

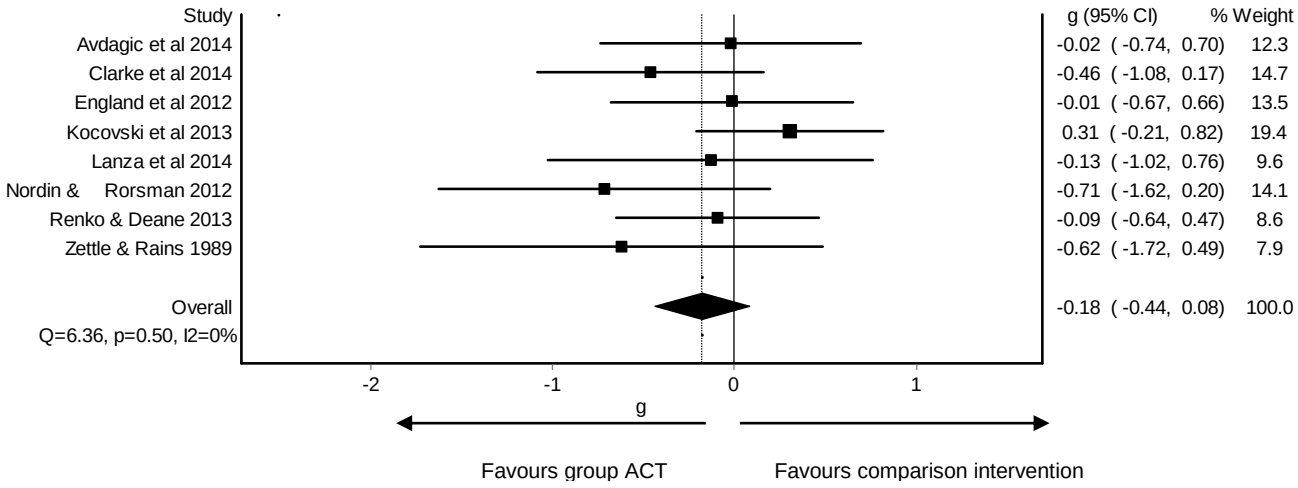


Figure 7. Forest plot for overall active follow-up effect sizes

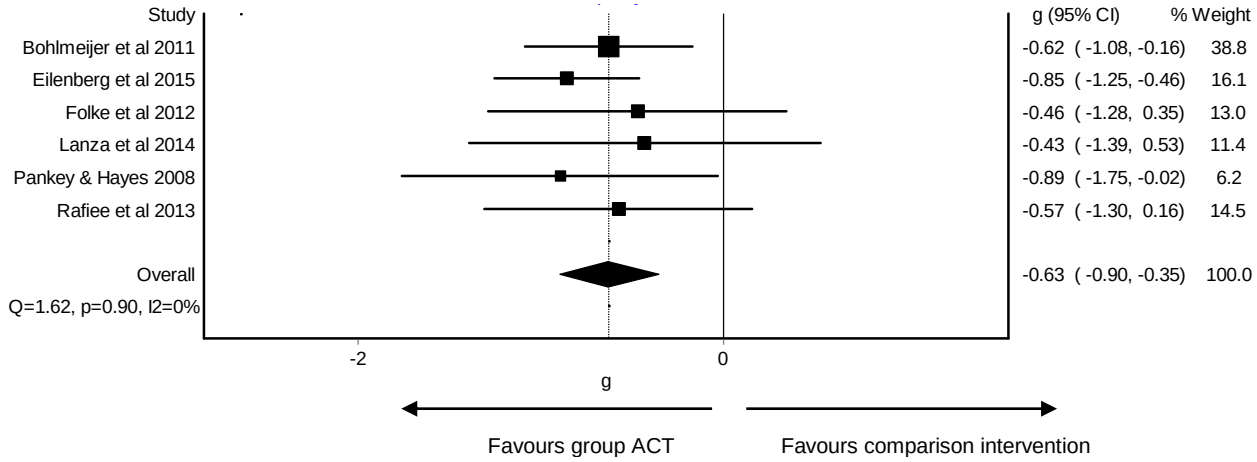


Figure 8. Forest plot for overall non-active follow-up effect sizes

6.9 Anxiety and depression at follow-up

Ten studies reported follow-up data for anxiety and depression. Follow-ups ranged from 1-18 months, with a mean of 5.3 months. The final follow-up data point for each study was included (Table 1).

6.9.1 Subgroup analysis of between-group outcomes for follow-up of active comparison interventions.

In the pooled analysis of between group effect sizes for ACT groups vs active comparison controls for anxiety and depression an effect size of -0.13 (CI = -0.44 – 0.17) was found. A non-significant heterogeneity within this comparison was identified (Q = 4.92; p = 0.43; I^2 = 0%).

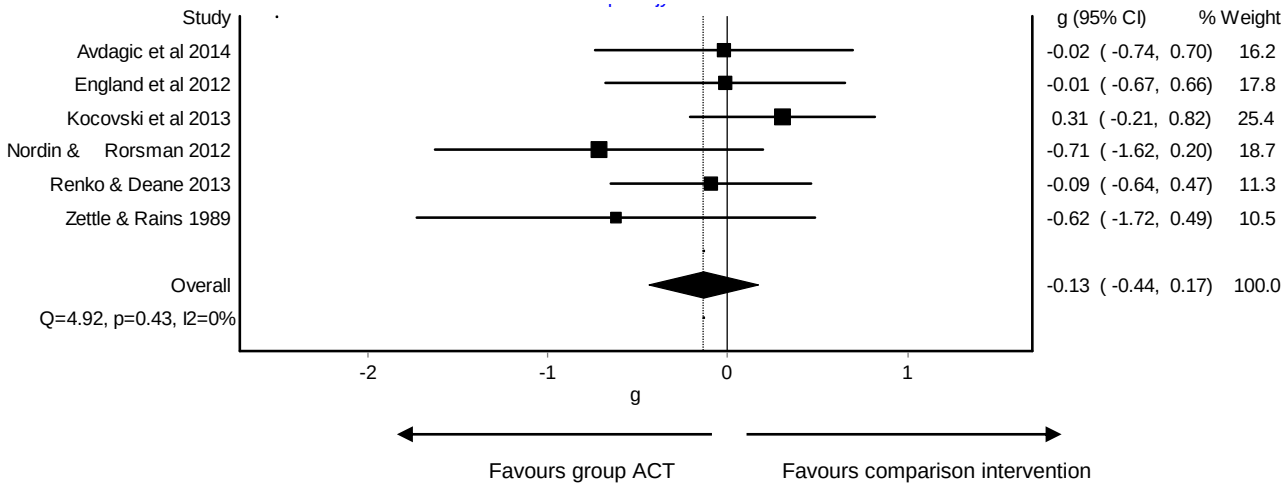


Figure 9. Forest plot for active comparison subgroup analysis of anxiety and depression outcomes at follow-up

6.9.2 Subgroup analysis for between-group outcomes for follow-up for non-active comparison interventions

In the pooled analysis of between group effect sizes for ACT groups vs non-active comparison controls for anxiety and depression an effect size of -0.63 (CI = -0.93 – -0.34) was found. A non-significant heterogeneity within this comparison was identified (Q = 1.13; p = 0.77; I^2 = 0%).

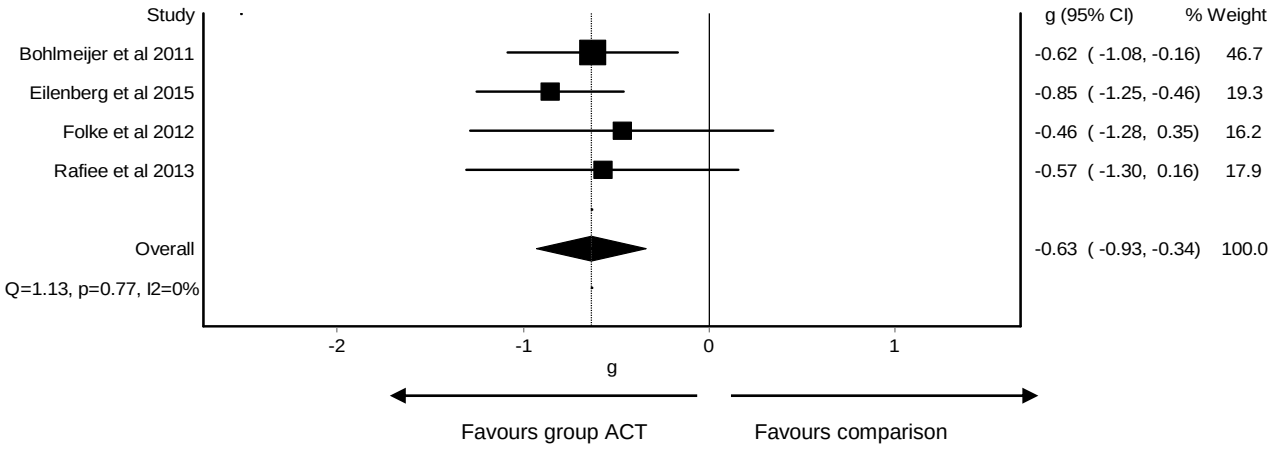


Figure 10. Forest plot for non-active comparisons outcomes at follow-up

6.10 Between-group outcomes for wait-list/TAU controls on quality of life measures

Our initial aims were to look at the efficacy of group-based ACT interventions on mental health indices as well as quality of life (QoL) measures. Only three studies used QoL measures; one comparing ACT to an active treatment (Avdagic, 2014) and two comparing ACT to a non-active control (Eilenberg, 2012 & Folke, 2012). Therefore, a quantitative analysis of QoL measures could not be conducted.

6.11 Publication bias

Of the 18 studies included in this meta-analysis, three studies were unpublished degree dissertations/thesis (Renko and Deane, 2013; Pellowe, 2006; Pankey and Hayes, 2009). When grouped by source, published studies produced a higher overall effect size (ES = -0.63, CI = -0.99 - -0.28) than that of the grey literature (ES = -0.40, CI = -0.91 – 0.12). Despite the small amount of studies, these could be assumed to be representative of any missing studies within this review, which may suggest some bias is present.

Duplication articles were identified in two of the included studies (Lanza, 2014; Bohlmeijer et al.,2011). These were removed at the full-text screening stage after contacting the authors to make sure they were indeed the same data sets, thus reducing duplication bias.

Two funnel plots were created using the standard error of the intervention effect estimate. One examined small study effects of the between groups outcomes post-intervention (for anxiety and depression; Figure 11). The other analysed small study effects of the follow-up effect sizes, again excluding the four studies not investigating anxiety and depression (Figure 12). Visual examination of the funnel plots found possible publication bias, with both graphs showing asymmetry, particularly in the bottom right where small studies producing non-significant results would be present.

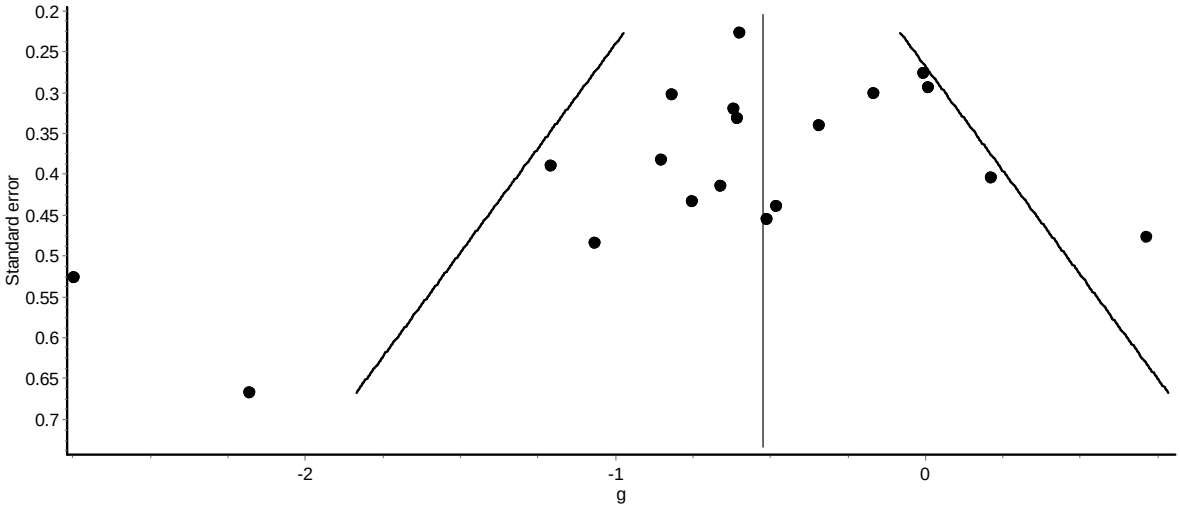


Figure 11. Funnel plot of standard error by Hedge's *g* for between groups effect sizes at post-intervention

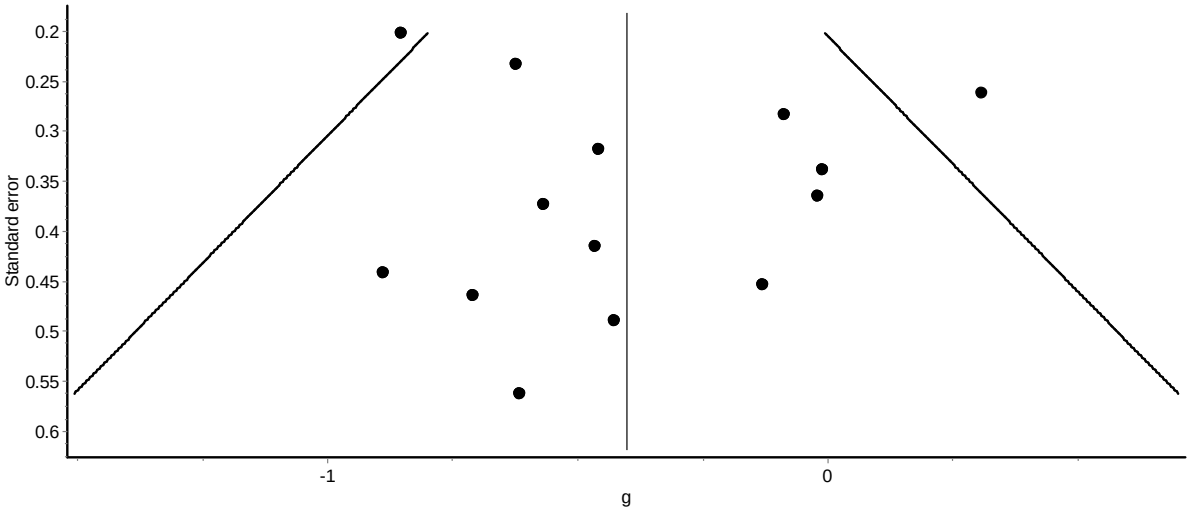


Figure 12. Funnel plot of standard error by Hedge's *g* for between group effect sizes at follow-up

However, Rosenthal's (1979) fail-safe N estimate indicated that 201 studies, in which the intervention effect was zero, would be needed to reduce the overall effect size to a level of non-significance. This suggests that bias is unlikely.

7.0 Discussion

7.1 Summary of findings

The aim of this review was to explore the efficacy of delivering ACT in group formats to adults with mental health disorders, when compared to active and non-active controls. The findings suggest that, from the eighteen RCTs included, ACT-based group interventions had a large effect on symptom reduction when compared to non-active comparisons at post-treatment (Hedges g = -0.91), and a moderate effect when compared to non-active comparisons at follow-up (Hedges g = -0.63). Additionally, there was a small effect in favour of ACT-based groups compared to active treatment controls at post-treatment (Hedges g = -0.25) and no effect (Hedges g = -0.18) when compared to active treatment controls at follow-up. These results

indicate that ACT-based groups produce comparable effects to established treatments.

The review aimed to encompass a broad range of clinical diagnoses. This was because ACT takes a functional approach to influencing behaviour that applies across a broad spectrum of clinical problems. However, the extent to which these findings can be applied to a range of mental health disorders was limited. Out of the 18 RCTs included, 14 focussed on anxiety and depression. Only one study was available for each of the remaining mental health disorders.

When considering the fourteen RCTs, which focussed on anxiety and depression, a moderate effect size on symptom reduction was found when comparing ACT to non-active control conditions at post-treatment (Hedges g = -0.66), and a moderate effect when compared at follow-up (Hedges g = -0.63). There was a small effect in favour of ACT-based groups compared to active treatment controls at post-treatment (Hedges g = -0.31) and equivalent effects (Hedges g = -0.13) when compared at follow-up. These results again indicate that ACT-based groups produce comparable effects to established group-based treatments. In addition, although we excluded studies based on specific disorders from the sensitivity analysis, there was very little difference in effect sizes between these studies and the majority of studies which looked at anxiety/depression. This conceptually fits into the ACT model which suggests a transdiagnostic approach to mental health issues; drawing on the contextual nature of the issue rather than the disorder itself.

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7.2 General discussion

This review demonstrates the efficacy of using ACT-based groups when compared to non-active and active treatment interventions. As well as demonstrating a small advantage at post-treatment, ACT-based groups may also offer additional advantages, such as facilitating comorbid difficulties within the same group and functionally addressing difficulties as opposed to focussing on modifying dysfunctional cognitions and reducing symptoms. ACT-based groups may also offer an alternative treatment modality for those individuals whereby traditional behavioural and cognitive approaches have been unsuccessful. However, the equivalence in effects at follow-up may prevent service providers, who already have established groups within services, from implementing ACT-based groups, unless consideration of these additional advantages are understood.

Although the majority of studies showed an effect in favour of the ACT group, three studies showed an effect in the opposite direction. In the study by Kocovski (2013), the CBT group was superior than the ACT group at follow-up (ES = 0.13, CI = -0.21, 0.82). However, the authors conclude that these groups did not differ significantly, when controlling for pre-treatment scores. In the study by Lanza (2014), a significant change in favour of the CBT group was observed at post-treatment (ES = 0.22, CI = -0.58, 1.01). This reduced at follow-up, compared to the ACT group where the effect size was maintained. This suggests the ACT group produced sustained improvements six months after the group, compared to the CBT group. In the study by Tamannaeifar (2014), a large effect size (g = 0.72; CI -0.22, 1.65) was observed in favour of CBT. However, in their own analysis a significant difference between the two groups at post-treatment was not found. This may be a result of small sample

size. Their study also suffered from very likely risk of bias (particularly in relation to unreported withdrawals/drop-outs, intervention integrity and analysis) which may have inflated the size of treatment effect.

Within-group effect sizes of the ACT group were calculated using the test retest correlation for each of the studies primary outcome. Effect sizes ranged from 0.00 – 4.81, signifying greater gains in certain samples than others. Most studies demonstrated medium effect sizes or greater, suggesting ACT-based groups are an acceptable format for change to occur.

Both the Nordin and Rorsman (2012) and the Tamannaeifar et al., (2014) studies were excluded as outliers within the ACT versus active treatment comparison at post-intervention. These studies are somewhat different from the other studies in a variety of ways. First, both studies included a smaller overall sample size than the remaining studies. Second, Nordin and Rorsman (2012) used relaxation training as their active control comparison. It could be argued such therapeutic intervention lacks the robustness of other therapies such as CBT, thus inflating the effect size in favour of ACT. Indeed, relaxation training is sometimes one component of a multi-faceted CBT intervention. The Tamannaeifar et al. (2014) study was assessed as having poor quality, with very likely risk of bias across multiple domains, including confounders, withdrawals/ drop-outs, intervention integrity and analysis. Questions therefore remain regarding the applicability of such results.

Studies by Mojtabaie and Asghari (2014) and Yadegari (2014) were excluded as outliers from the ACT versus non-active treatment comparisons at post-intervention. These studies are also somewhat different from the other studies in a variety of ways. First, both studies included a smaller overall sample size than the remaining studies.

Secondly, neither studies included a follow-up, whereas the remaining studies did. Mojtabaie and Asghari (2014) focussed on depression within a group of woman with breast cancer. This sample maybe somewhat unique compared to the other studies. Yadegari (2014) focussed on anxiety within young adults. Their mean age was lower than any of the remaining studies. The above differences may account for the heterogeneity accounted for within these studies.

It is important to note that the ACT model does not aim to reduce symptoms as the target of its intervention. Despite this, the majority of studies focussed on symptom reduction and found a favourable outcome for ACT-based groups. Another aspect of therapeutic intervention is to increase functioning which can be measured by focussing on QoL. This is particularly important to the ACT model which aims to increase values-based action that enhances long-term desired qualities of life (Hayes, Luoma, Bond, Masuda, & Lillis, 2006). It would be of interest to observe studies using ACT within a group format from this angle, of which there are currently very few.

Fifteen of the 18 studies were conducted after 2010. This suggests an increased interest in this area. A strength of this review is that substantial effort was made to identify relevant studies to be included within this meta-analysis. This included searching multiple databases, emailing the ACBS list serv and contacting authors. The study design was limited to RCTs. RCTs are considered the 'gold standard' in research design and prevent bias through random assignment and comparison with a control condition. Outcome measures were valid and reliable. A high inter-rater reliability was observed for the studies quality ratings, indicating substantial confidence in our risk of bias assessments.

7.3 Limitations

The included RCTs were homogeneous in terms of clinical diversity and statistical heterogeneity. This limits the generalisability of the findings to predominantly woman (77.1%), within Western societies, suffering from anxiety and/or depression. There was a limited range of mental health disorders which also reduces the generalisability of results. Therefore, further studies looking at the use of ACT-based groups in more diverse populations and measuring other outcomes than symptom reduction would add to the texture of a similar review in the future. The risk of bias index was adapted from the EPHPP, meaning it was not validated. However, as it included all EPHPP criteria plus additional conditions, it could be argued that it was a more conservative measure of overall risk of bias.

The quality of the studies varied. The main source of risk of bias came from limited blinding methods. Although double blinding methods are difficult to implement in psychological research due to participants playing an active involvement in therapy and therefore knowing what intervention they are receiving, single blinding of the outcome rater could have been implemented to avoid bias. Seven of the eighteen studies did not report sufficient information on the experience or supervision of the group facilitators. This could contribute to group outcome as it could be hypothesised that the competency of the facilitator may have a strong prediction on treatment success.

This analysis may be open to several types of publication bias. First, the review was limited to studies written in English. Therefore, language bias was potentially introduced which can inflate the methodological quality of studies, increase sample

size and reduce the significance of results (Jüni, Holenstein, Sterne, Bartlett, & Egger, 2002). However, it is unlikely that this exclusion, due to limited resources for translation, had a substantial impact on the effect estimates. Jüni et al., (2002) investigated the impact of language bias on treatment effects and found that the exclusion of non-English language trials had little effect on summary treatment effect estimates.

Funnel plots asymmetry may be an indication that non-significant studies were less likely to have been published. However, the number needed for non-significance was high which gives us some confidence in the applicability of the effect sizes found.

Study selection was only conducted by one author. PRISMA highlights that the use of just one author may increase the possibility of rejecting relevant reports. Nevertheless, it is likely that all relevant studies were captured within this review, given the additional efforts to identify studies beyond electronic searches. Still, it is worth noting that although attempts were made to contact study authors, to obtain unpublished studies and raw data, only three out of eighteen responded. The results may therefore be open to publication bias, with significant findings being more likely to be published.

Upon closer examination, two studies deviated from the pre-specified definitions and exclusion criteria. Three participants in the study conducted by Folke (2012) were found not to be depressed at pre-treatment, using the Beck and Steers (1993b) proposed diagnostic intervals. Furthermore, the study by Pellowe (2006) included a group consisting of only two participants. These discrepancies are small but

noteworthy. Clearer operationalisation of definitions in combination of the exclusion criteria may have prevented this error from being made.

7.4 Comparisons with other meta-analysis

This trend seems to be in line with other meta-analyses. A-Tjak et al., (2015) compared eight RCTs looking at anxiety/depression from a larger meta-analysis of 39 studies and, using similar criteria, found an effect size of g = 0.37 (CI: 0.04 - 0.70) in favour of ACT when compared to pooled control conditions and time. The review combined studies using both individual and group delivery formats. When the data from this review were pooled across control conditions and time a similar effect was found (g = -0.42, CI: -0.58, -0.25). Confidence intervals were narrower in this review which may be a result of a bigger sample size compared to the A-Tjak review (n = 983 versus n = 378, respectively). Yet another meta-analysis by Hacker, Stone & MacBeth (2016) compared 67 RCTs looking at anxiety and depression studies. Using a random-effects cumulative meta-analysis they found an overall effect size of d = -0.04 (CI = -0.21, 0.14) for anxiety and d = 0.26 (CI = -0.06, 0.56) for depression at post-treatment in favour of ACT when compared to active treatment controls. These effect sizes were smaller than the combined effect size of g = -0.31 at post-treatment that was demonstrated by this review. Again, the review incorporated a mixture of individual and group delivery formats which may go some way in explaining the difference in effects.

7.5 Implications for clinical practice

This review suggests that ACT-based groups are a viable alternative to other active treatment groups, especially when considering patients with anxiety/depression. The average length of treatment was nine sessions (range = 4 - 16). This is relatively short, which is promising for services wishing to use ACT-based groups as a way of increasing patient capacity in an economical but clinically effective way. However, Kocovski (2013) highlights the practical difficulties of groups such as the need for set times which may increase attrition, thus reducing cost-effectiveness. The majority of studies included in this review did have low attrition rates, suggesting that group-based ACT is a feasible delivery format. However, the range was large, suggesting that some ACT groups retain people better than others. Factors that may influence attrition may be the complexity of the sample (e.g. Morton), timing of the group, travel issues (e.g. Kocovski, 2013) or other commitments such as attending university (e.g. Renko & Deane, 2013). Another implication of this review is that it demonstrates that ACT-based groups have sustained improvements at follow-up which may again be attractive to healthcare providers.

7.6 Recommendation for future research

Based on the studies included within the review, several suggestions have been recommended to improve the quality of research design within this area. First, many studies did not provide *a priori* power calculations or report that sufficient power was not achieved. Power calculations are therefore recommended to estimate number of subjects needed within studies to detect treatment effect and avoid Type II errors. Second, the use of blinding was unreported in many of the studies. The unreported

use of blinding may be a result of suboptimal reporting quality which may not reflect the actual quality of the study itself. Future research needs to highlight what blinding methods were used. Blinding is a requirement for the CONSORT (Schultz, Altman & Moher, 2010) minimum set of recommendations for reporting randomised control trials. Third, many of the samples were recruited via self-referral. Further studies may wish to recruit samples in a more systematic way, such as random selection from a comprehensive list of individuals in the target population (as recommended by EPHPP). This would increase likelihood of the sample being representative of the target population.

There are several questions that this review does not address. First, what is the optimal number of treatment sessions for group-based ACT and does this differ from individual therapy as well as alternative therapeutic modalities? Second, do groups that include individuals with the same diagnoses work better than groups that have different disorders? Similarly, is it better to include individuals who are functionally similar or diagnostically similar? Third, do ACT-based groups provide similar results across the spectrum of anxiety and/or depression, or does symptom severity have an impact on outcome? Finally, would some individuals do better in a group format than others and if so, could we triage individuals at the point of referral based on measurable traits to best inform delivery format? Future research should consider testing the above questions to further enhance our understanding of what works best for whom. A further avenue would be to develop RCT designs that isolate elements of treatment or measure within treatment effects and mediators. This would help us dismantle components of multi-faceted treatments to understand processes of change within ACT group interventions and its comparators.

8.0 Conclusions

To the best of our knowledge, this is the first meta-analysis to examine the clinical efficacy of group-based interventions for mental health disorders using ACT. Considering risk of biases and limitations identified during the critical appraisal process, broadly speaking, this review indicates that group-based ACT is an efficacious intervention for anxiety and depression, with emerging evidence for its utility across other mental health disorders.

9.0 Funding

This review was completed as part of a course requirement to obtain a Doctorate in Clinical Psychology at the University of Edinburgh.

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Part B: Empirical Research Study[1, 2]

Evaluating Acceptance and Commitment Therapy (ACT) in the form of a Self-Help Manual with Minimal Telephone Support for Anxiety and Depression: A Randomised Controlled Trial.

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[1] For ease of reference, the self-help manual 'Valued Living' has been supplied for thesis examination in Appendix 14, but would be excluded for publication.

[2] The Thesis Research Protocol (required as part of the Doctoral Thesis) can be viewed in Appendix 7.

Evaluating Acceptance and Commitment Therapy (ACT) in the form of a Self-Help Manual with Minimal Telephone Support for Anxiety and Depression: A Randomised Controlled Trial.

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1.0 Highlights

- A guided self-help intervention for anxiety/depression was examined.
- Randomisation into the intervention or treatment as usual was conducted.
- Guided self-help did not produce significant change on outcomes.
- Small sample size and large attrition limit the results.

2.0 Abstract

Background: A growing body of evidence suggests that ACT is an effective intervention for the treatment of mental health disorders, such as anxiety and depression. However, it is unknown whether ACT is a suitable intervention when delivered in a guided self-help format.

Method: A randomised controlled trial evaluated an ACT-based guided self-help intervention in a clinical sample of participants with anxiety/depression. The

intervention consisted of a self-help manual and two telephone calls from a therapist. The control arm consisted of treatment as usual. Mixed analysis of variance and clinically significant and reliable change examined outcomes on symptoms, quality of life and process measures. Missing data was addressed using multiple imputation.

Results: Forty-nine individuals with anxiety/depression were randomly allocated to a six-week ACT intervention (n = 24) or treatment as usual (n = 25). Participants were predominantly female (65.3%) and between the ages of 18 - 62 years (*M* = 36.91, *SD* = 13.59). Over 80% of participants reported experiencing both anxiety and depression. Data from 27 participants (ACT = 12, TAU = 15) was available at post-intervention. Participants showed no improvement in symptoms or quality of life.

Conclusion: The null findings may be due to the severity of the sample or a result of small sample size and high attrition. Larger scale research incorporating follow-up data would address the methodological limitations of this study.

Keywords: Acceptance and Commitment Therapy, ACT, Self-help, Bibliotherapy, Anxiety, Depression.

3.0 Introduction

Traditional Cognitive-Behavioural Therapy (CBT; Beck 1987) and Acceptance and Commitment Therapy (ACT; Hayes, Strosahl, & Wilson, 1999) have both been shown to be effective in the treatment of common mental health disorders. CBT has a strong evidence base for depression (Cuijpers et al., 2012), and anxiety (Clark et al., 2003; Barlow, Gorman, Shear, & Woods, 2000; Foa, 2005; Borkovec & Costello, 1993; Bryant, Moulds & Nixon, 2003). ACT has an emerging evidence base,

associated with consistent large effects when compared to wait-list or inactive controls across a broad spectrum of disorders, including depression (Bohlmeijer, Fledderus, Rokx & Pieterse, 2011), and anxiety (Dalrymple & Herbert, 2007; Meuret, Twohig, Rosenfield, Hayes, & Craske, 2012; Twohig et al., 2010; Hayes-Skelton, Roemer, & Orsillo, 2013). Since 1986, there have been over 170 randomised controlled trials (RCTs) comparing ACT to non-active and active treatments (Hayes, 2016). Preliminary evidence suggests that, when directly compared, ACT is at least as effective as CBT, across a variety of problems. These results were predominantly obtained from studies evaluating individual therapy. A review by Ruiz (2012) analysed 16 interventions comparing ACT to CBT across a diverse range of disorders and found a significant effect of 0.40, in favour of ACT. In contrast, Öst (2014) reviewed 22 randomised studies comparing ACT to CBT and found a non-significant effect of 0.16. The disparity in effect sizes were hypothesised to be due to the inclusion of additional studies in the Öst meta-analysis and the exclusion of four studies included in Ruiz's meta-analysis, which yielded moderate-to-large effects. Even if a conservative estimate is taken; that ACT is equivalent to CBT across outcomes, this provides a platform with which to examine whether such results may extend to alternative delivery formats.

3.1 Low-intensity interventions

The conventional format for delivering CBT/ACT is individual therapy. However, with a growing population and increasing demands on health care resources, capacity to provide this is increasingly challenging. This is a global issue faced by health care services around the world. Alternative delivery formats are therefore required.

Bibliotherapy provides a low-intensity intervention whereby a protocol can be delivered repeatedly. A meta-analysis containing 14 studies found a large effect size at post-treatment (0.84) when comparing cognitive and behavioural-based self-help interventions to non-active control comparisons (den Boer, Wiersma & Van den Bosch, 2004). There were equivalent effects (-0.03) when comparing self-help to other active delivery formats, such as group therapy, suggesting self-help may be as effective as alternative treatment modalities.

Anxiety and depression are two of the most prevalent mental health disorders (Martin, 2003; Vos et al., 2013), with an estimated 55-77% of cases classed within the mild-to-moderate category (Kessler et al., 2005). Guided self-help (GSH) is the recommended intervention in treating mild-to-moderate anxiety/depression (NICE, 2009; 2011; NES, 2011). The primary therapeutic modality is currently CBT, due to its evidence base. For example, Bilich, Deane, Phipps, Barisic and Gould (2008) evaluated the effectiveness of a CBT GSH manual (with either a 5 or 30-minute weekly telephone call). Significant improvements were found on all outcome measures at 8-week post-treatment and 4-week follow-up, compared to wait-list controls. Due to the success of CBT-based GHS interventions, such results may translate to acceptance-based GHS interventions.

3.2 Acceptance and Commitment Therapy

ACT is an empirically based psychological intervention which was developed in parallel with a basic science approach to language and cognition called Relational Frame Theory (RFT; Blackledge, 2003). RFT attempts to model the influence of language and cognition on behaviour, from within behaviour analysis, rather than

postulating hypothetical explanatory constructs such as schemas or core beliefs as causal agents. The goal of ACT is to increase psychological flexibility which is defined as, "the ability to contact the present moment more fully as a conscious human being, and to change or persist in behavior when doing so serves valued ends" (Hayes, Strosahl, Bunting, Twohig & Wilson, 2004, p.5). By centring on six core processes (acceptance, cognitive defusion, increasing self-as-context, connecting with values, being present and committed action), ACT increases psychological flexibility by promoting workable behaviour in tune with one's chosen values. It focuses on "positive psychological skills" (p. 226), rather than targeting psychopathology, such as unwanted experiences and feelings (Lundgren, Dahl & Hayes, 2008). Change occurs by altering the function of inflexible internal systems and the individual's relationship to them (Hayes, Luoma, Bond, Masuda & Lillis, 2006).

Such approach diverges from CBT which targets the content, rather than the context, of cognitions and emotions, attempting to modify dysfunctional thinking processes and reduce symptoms (Beck, 1967). Studies have shown the paradoxical effects of trying to reduce or avoid contact with unwanted sensations, emotions or cognitive events; it can serve to maintain or increase them (e.g. Abramowitz, Tolin & Street, 2001). As such, ACT may offer an alternative theoretical approach. Investigating whether ACT can be utilised within low-intensity contexts would increase its utility across delivery formats.

3.3 ACT and low-intensity interventions

Promising results have been found in low-intensity studies investigating the effects of ACT for smoking cessation (web-based; Bricker, Wyszynski, Comstock &

Heffner, 2013), depression (web-based, Carlbring, 2013; manual and email support, Fledderus, Bohlmeijer, Pieterse & Schreurs, 2012), chronic pain (web-based, Buhrman, 2013, Johnston, Foster, Shennan, Starkey & Johnson, 2010; manualised, Thorsell, 2011), irritable bowel syndrome (Manual; Gillanders, Ferreira, Angioni, Carvalho, & Eugenicos, *in press*) and tinnitus (web-based; Hesser et al., 2012). A meta-analysis identified 15 RCTs that used acceptance-based and/or mindfulness-based components within a self-help format (Cavanagh, Strauss, Forder & Jones, 2014). Studies focussed on both physical and mental health populations with 12 studies looking at anxiety/depression. The analysis revealed small-to-medium effects, favouring ACT, with significant reductions in anxiety and depression. However, ACT and mindfulness studies (a single process within the ACT model) were combined. Additionally, 'pure' ACT-based interventions and GSH interventions were combined. Coull and Morris (2011) argue that GSH can be regarded as a more intensive treatment, with therapist input impacting on the effectiveness of the outcome. Indeed, a review by Newman, Szkodny, Llera and Przeworski (2011) suggested that minimal-contact therapies provide optimal efficacy for mood and anxiety disorders when accounting for attrition and compliance. Pure self-help interventions were found to be effective for only motivated clients with anxiety disorders. Therefore, research that delineates pure and GSH interventions is needed.

A study by Ritzert et al., (2016) evaluated an ACT self-help manual for anxiety. It found significant improvements on all outcome measures at posttreatment, compared to wait-list controls. These gains were maintained at 9-month follow-up. However, the sample was not clinical, with recruitment occurring mainly online. It has been

found that CBT-based GSH interventions for anxiety/depression were less effective in clinical samples, compared to samples recruited via advertisements (Coull & Morris, 2011). A diagnosis of anxiety was self-reported by 55.9% of participants but this was not further validated. Nevertheless, pre-scores indicated that participants were experiencing severe levels of anxiety. This was also a pure self-help intervention, which has been shown only to be effective with motivated clients (Newman et al., 2011). This may explain the 71.5% attrition rate at follow-up.

An ACT GSH study by Fledderous, Bohlmeijer, Pitrese and Schreurs (2012), demonstrated significant moderate-to-large effect sizes (d = 0.51-1.00) when comparing a nine-week intervention with email support to a wait-list condition. The sample was recruited through newspaper advertisements and included individuals with mild-to-moderate anxiety/depression. Could such effects be replicated in individuals recruited from a clinical setting?

3.4 The proposed study

So far, studies have evaluated ACT-based self-help in non-clinical settings, using pure self-help and email support for individuals with anxiety/depression. This study aimed to add to the evidence by investigating the acceptability of using an ACT-based GSH manual within a clinical sample of individuals with anxiety/depression. It was hypothesised that participating in such intervention would significantly improve quality of life (QoL) compared to a non-active control group. Based on previous research (Ritzert, 2016; Fledderus et al., 2011) it was also hypothesised that the ACT GSH intervention would significantly reduce anxiety and depressive symptoms, compared to the control group.

4.0 Methods

4.1 Trial design

This was a multi-site, rater-blinded, between-groups, parallel design conducted in Scotland, United Kingdom. Participants were assigned to either an ACT group or treatment as usual (TAU) condition by means of restricted randomisation using an equal allocation ratio (1:1). Participants were assessed at pre-treatment and post-treatment, six weeks apart. The protocol and consent process received approval from the NHS Research Ethics (Reference: 15/WS/0056; Appendix 8). The protocol was specified *a priori* and was registered on ClinicalTrials.gov (NCT02449759; Appendix 9).

4.2 Participants and procedure

Participants were recruited between April 2015 to April 2017 through three National Health Service (NHS) primary care adult psychology outpatient clinics located in Forth Valley, Fife and North West Glasgow. The first site, within Forth Valley, is semi-rural, within the central belt of Scotland, with a population of 281,000. The second site, within Glasgow, is a major commercial city with a population of over 600,000. The third site, Fife, is semi-rural and is Scotland's third largest local authority area by population; over 350,000. Participants were referred to a primary care service via their General Practitioner (GP) or through self-referral and had opted to receive either individual or group therapy for anxiety/depression. A clinical sample was chosen so that results could be generalised to such populations presenting within mental health services. Anxiety and depression were chosen as the two most common disorders that characteristically present within primary care clinics. Individuals were informed by the services that they may be contacted to take

part in research whilst on the waiting list. Patients were posted an information sheet (Appendix 10), consent form (Appendix 11), and questionnaires. Participating in this study did not affect the wait time for usual care. Figure 1 shows the CONSORT flow chart of participants throughout the study (Moher, Schulz & Altman, 2001). The CONSORT checklist of included items can be seen in Appendix 12.

4.3 Eligibility criteria

To be eligible for this study, the following criteria had to be met:

a) Adults (18 years)

b) mild-to-moderate anxiety (≥ 4 and ≤ 7) and/or mild-to-moderate depression (≥ 5 and ≤ 10), on the DASS-21

c) no substantial risk of self-harm, suicide or risk to others

d) no intellectual impairment

e) adequate English proficiency

f) able to freely give informed consent

g) not commenced or changed medication within the last three months

h) not received therapy using an ACT approach within the last 6 months

i) not have a primary diagnosis other than anxiety/depression

j) not referred for specialist therapies

k) not taking part in any other study

These were assessed through a self-report questionnaire (see Appendix 13), standardised questionnaires and the referral letter.

4.4 Changes to trial outcomes

Six months after the trial commenced it became apparent that the inclusion criteria's severity classification was too restrictive. It was subsequently removed. This was considered a major amendment by the ethics committee who approved such change. Due to the impact on recruitment figures, two further sites were added, as described above.

4.5 Sample size

G*Power (Version 3.1.9.2; Faul, Erdfelder, Lang & Buchner, 2007) was used to compute a sample size. Sample size was calculated for the primary outcome measure of QoL. Based on a mixed ANOVA, a large effect size (f = .35) was chosen (Cohen, 1992). This was based on prior studies which demonstrated large effects (Fledderus, 2012; Johnston et al., 2010; Carlbring et al., 2013). Probability was set at 0.05 and power at .80. Based on these assumptions a sample size of 18 per condition was needed. This sample estimate was increased to 22 people per group (n = 44) to account for attrition.

4.6 Outcome measures

Participants completed a demographic questionnaire which also covered presenting problems and duration of problems (Appendix 13). Seven standardised outcome measures were also completed.

4.6.1 Primary outcome measure

The *World Health Organisation Quality of Life-BREF* (WHOQOL-BREF; Skevington, S.M., Lotfy, M., & O'Connell, K.A., 2004) is a 26-item scale covering physical health, psychological health, social relationships and environment. Items are

scored on a five-point Likert scale, ranging from 1-5. It is recommended for use in clinical trials. The scale has excellent psychometric properties of reliability and validity. According to Skevington et al., (2004), the WHOQOL-BREF showed good internal consistency (≥0.80 for physical, psychological and environmental and 0.68 for social relationships) when sampled across 23 countries (n = 11,830). Permission to use the WHOQOL-BREF was obtained in December 2014.

4.6.2 Secondary outcomes

The *Acceptance and Action Questionnaire II* (AAQ-II; Bond et. al, 2011) is a seven-item, uni-dimensional, self-report questionnaire, which measures experiential avoidance/psychological flexibility. The AAQ-II addresses the AAQ-I's problems with obtaining significant alpha levels and has been shown to measure the same concept (*.97).* From a total of 2816 participants (across 6 samples), the AAQ-II has good test re-test reliability of .81 - .79.

The *Mindfulness Attention Awareness Scale* (MAAS; Brown & Ryan, 2003) is a 15-item, self-report questionnaire which measures psychological awareness. It has good convergent and discriminant validity as well as high internal consistency (.80 to .90, Cronbach's alpha) and test-retest reliability (.81).

The *Cognitive Fusion Questionnaire (CFQ; Gillanders, Bolderston, Bond et al. 2014)* is a seven-item, self-report questionnaire. It assesses fusion with cognition. It shows good factor structure, test re-test reliability (.80) and internal consistency (.88 - .93).

The *Engaged Living Scale (ELS; Trompetter et al., 2013)* is a 16-item, self-report questionnaire which measures values and committed action. It is based on two factors; valued living (10 items) and life fulfilment (6 items) and was evaluated using a non-clinical (*N* = 439) and clinical sample (*N* = 238) consisting of chronic pain patients. It shows good construct validity and internal consistency (.87 - .91).

The *Clinical Outcomes in Routine Evaluation (CORE; Barkham et al., 1998)* is a 34-item self-report questionnaire which measures overall psychological distress across four domains: well-being (4 items), symptoms (12 items), functioning (12 items) and risk (6 items). The CORE-OM is routinely used within 500 services within the UK (CORE IMS, n.d.). It has good internal and test-retest reliability (0.75-0.95), as well as good convergent validity with seven other measures (Evans et al., 2002).

The *Depression, Anxiety and Stress Scales (DASS-21; Lovibond & Lovibond, 1995)* is a 21-item self-report measure consisting of three scales which assess depression, anxiety and stress. Each scale has good reliability (Cronbach α's = 0.88, 0.82 & 0.90) and good convergent and divergent validity (Lovibond & Lovibond, 1995). The DASS-21 is recommended for research and allows both anxiety and depression to be measured within the same questionnaire.

4.7 Intervention

4.7.1 ACT group

The intervention consisted of a 58-page manual titled ‘Valued Living’. It was written to be evaluated in this study. It drew upon information derived from Hayes et al., (1999) as well as existing ACT manuals (e.g. Hayes & Smith, 2005; Harris 2008).

There were six chapters, each of which focussed on one of the six core processes of the ACT model. Case studies, metaphors and experiential exercises were included. The manual can be viewed at: https://contextualscience.org/selfhelp_manual_for_anxiety_andor_depression. The manual was written by the first author (SF), a specialist five-year clinical psychology doctoral trainee who had completed ACT training, attended four experiential workshops, and received two years of ACT supervision by experienced therapists. Contributions to writing and editing were made by the third author (DG), an international ACT expert. It was reviewed by 10 clinical psychologists who provided feedback on the accuracy, readability and clarity of content. Changes were made accordingly. A readability calculator (www.readabilityformulas.com) on a sample of text indicated that the manual was 'fairly easy to read' (Flesch Reading Ease = 69.6).

Participants also received two telephone calls from the first author during weeks two and five of the intervention, to guide them through the manual, check understanding and answer any questions. Fidelity to the therapy during the telephone calls was not formally measured but a list of questions were adhered to (Appendix 15). GSH was chosen due to evidence suggesting that minimal-contact therapies provide optimal efficacy for mood/anxiety disorders (Newman et al., 2011).

The manual was posted to participants and they were instructed to read one chapter each week. Weekly exercises were encouraged within the manual. Treatment adherence was measured by a self-report questionnaire. Participants were encouraged to date and sign when they had read each chapter. Progress was also monitored during the two telephone calls. All treatment was received free of charge with no incentives. The last participant completed the intervention in April 2017.

Table 1: A brief description of the 'Valued Living' manual chapters

Chapt.	ACT Process	Brief description
1	Acceptance	What is ACT? What have you tried so far? Creative hopelessness. A case study example. Internal vs. external struggles. Avoidance is unworkable. Amplifying suffering through control. Willingness as an alternative. *Metaphors used*: Quicksand & Sailing Boat. *Weekly tasks:* Monitoring difficult thoughts, feelings and sensations. Recording the effects of such efforts.
2	Cognitive defusion	Avoidance and giving up the struggle. Why we get stuck and healthy distancing. Strategies that allow flexibility. A case study example. Flexibility in attending to thoughts. *Metaphors used:* Tug of war with a monster & Hands as thoughts. *Weekly tasks:* Using suggested strategies and recording which ones worked well for which contexts.
3	Present moment awareness	What is mindfulness? Simply noticing exercises. A case study example. Staying connected. Mindfulness exercises: 5 senses, passing thoughts, mindfulness of the body. Practicing being present. *Weekly tasks:* Mindfulness practice sheet.
4	Self-as-context	The story of you. Another kind of self. Perspective shifting and connecting with the noticing you. *Metaphors used:* Rugby pitch (formerly the Chess Board metaphor). *Weekly tasks:* Taking an observing stance towards internal events.
5	Values	Direction of living. Becoming aware of what you value. My personal values. What am I willing to accept in order to move in the direction of my values? A case study example. *Metaphors used:* Compass, journey vs destination *Weekly tasks:* Creating value cards based on different domains (e.g. education, leisure, family, relationships etc.).
6	Committed action	Taking action. Goals setting. What is holding you back? A case study example. Problem solving. Strategies to help aid action. *Metaphors used:* Mountain metaphor *Weekly tasks:* Developing short, medium and long-term goals in the direction of personal values.
7	Summary	Conclusions. Where do we go from here? A summary of the core principles. Useful resources. Sources of additional help.

4.7.2 TAU group

The TAU group completed the same questionnaires at the same time interval as those in the ACT group. TAU was defined as receiving routine treatment by the GP or seeking additional help. A wait-list control design was not used as the relative effectiveness of the manual was not known and this would prolong waiting time to individual treatment. All participants were still waiting for individual therapy at the point of returning post-questionnaires.

4.8 Randomisation

Participants were allocated to the ACT or TAU group using a computer-generated randomisation list. The randomisation sequence was created using online software (www.randomizer.org) by the author (SR) who had no clinical involvement in the trial. It adopted a fixed block randomisation (blocks of eight) to ensure equal numbers in each group. The allocation sequence was concealed from the principal investigator (SF) assessing eligibility of participants. The sequence was kept digitally and was only accessible to the concealment researcher (SR). Once a participant had completed baseline questionnaires and assigned a unique participation number (UPN), the concealment researcher (SR) was phoned with the UPN and their allocation into the trial was given.

4.9 Blinding

Once assigned, the allocation was not concealed from the participants or the researcher (un-blinded). Data was returned anonymously and the assessor remained blind to treatment condition throughout the data collection and analysis process.

4.10 Statistical Analysis

Statistical Package for Social Sciences (SPSS, version 22; SPSS Inc. USA) was used for statistical analyses. Sociodemographic characteristics were summarised with descriptive statistics. Baseline between-group variables were analysed using independent *t*-tests and chi-square tests.

To examine both repeated measures as well as between group effects, outcomes were analysed using mixed design two-way 2 (condition: ACT or TAU) x 2 (outcome at baseline [T1] and post-treatment [T2]) analyses of variance (ANOVA). Clinically significant and reliable change index scores (Jacobson & Truax, 1991) were calculated, highlighting those individuals who dropped below clinical cut-off scores or reliably reduced based on post-treatment outcomes. Effect sizes were reported using Cohen's *d.*

5.0 Results

5.1 Baseline characteristics

There were 112 individuals who were assessed for eligibility. Sixty-three were not eligible: 43 did not fall in the mild-to-moderate bracket for anxiety/depression (before this exclusion was dropped), 19 scored high on risk and one reached the top of the waiting list before the trial commenced. GPs were informed of those presenting with risk. The remaining 49 participants (32 females and 17 males) were randomly allocated to either the ACT intervention (n = 25) or the control group (n = 24). Baseline demographics and clinical characteristics can be seen in table 2.

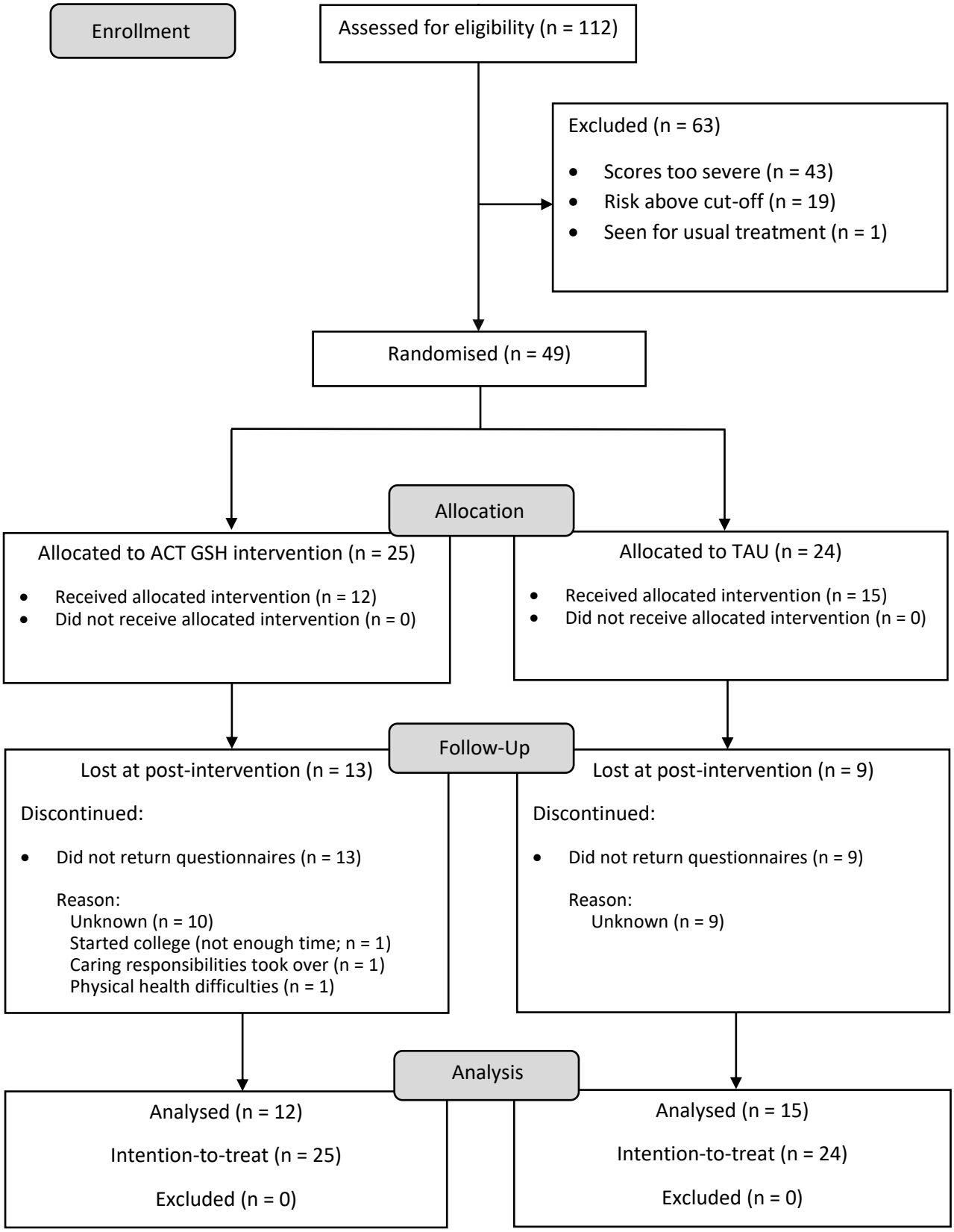


Figure 1: Consort flow diagram of participants throughout the trial comparing the ACT GSH group to the TAU group.

Around two thirds of participants (65.3%) were female, aged between 18 - 62 years (*M* = 36.91, *SD* = 13.59). The percentage of participants in a relationship (47%) was similar to those who were single (49%). Most participants classified their ethnicity as white (96%). Over half of the participants (57.2%) were in employment, 26.5% were unemployed, 14.3% were students, and 2% were retired. The highest level of education was high school for 20.4% of the sample, college for 34.7% and university for 44.9%. Over two-thirds of participants (71.4%) reported being on psychotropic medication and over half (57.1%) reported having comorbid physical health difficulties. Most participants reported experiencing both anxiety and depression (87.7%), with 8.2% of participants experiencing only anxiety and 4.1% experiencing only depression. Most participants (91.8%) reported experiencing additional mental health problems. Around one-fifth of the sample reported experiencing anxiety/depression for a duration of up to two years (18.4%), 36.7% experiencing anxiety/ depression for up to ten years and 44.9% experiencing anxiety/depression for more than ten years. The CORE-34 indicated that, at baseline, participants were experiencing moderate levels of psychological distress, (*M* = 62.51, *SD* = 17.27). The DASS indicated that, at baseline, the level of depression was moderate and the level of anxiety was severe.

There was one significant difference between groups at baseline. This related to gender, with more females in the ACT group compared to the TAU (see table 2). Such difference was down to chance as the sample was randomised. No further significant differences were found.

Table 2. Baseline demographics of participants

	All participants (n = 49)	ACT GSH (n = 25)	TAU (n = 24)	Comparison (t, X^2)
Age (years; *M, SD*)	36.91 (13.59)	33.80 (11.81)	40.15 (13.91)	t = 1.66, *p* = .102
Gender *n* (%)				
Female	32 (65.3)	20 (80.0)	12 (50.0)	X^2 = 4.86, *p* = .027
Male	17 (34.7)	5 (20.0)	12 (50.0)	
Marital status *n* (%)				
Married/Living together	23 (47.0)	14 (56.0)	9 (37.5)	X^2 = 1.73, *p* = .420
Single	24 (49.0)	10 (40.0)	14 (58.3)	
Divorced/Separated	2 (4.0)	1 (4.0)	1 (4.2)	
Ethnic origin *n* (%)				
Asian	1 (2.0)	0 (0.0)	1 (4.2)	-
Hispanic or Latino	1 (2.0)	1 (4.0)	0 (0.0)	
White	47 (96.0)	24 (96.0)	23 (95.8)	
Employment *n* (%)				
Full-time	22 (44.9)	9 (36.0)	13 (54.2)	X^2 = 1.88, *p* =.756
Part-time	6 (12.3)	3 (12.0)	3 (12.5)	
Student	7 (14.3)	5 (20.0)	2 (8.3)	
Not employed	13 (26.5)	8 (32.0)	5 (20.8)	
Retired	1 (2.0)	0 (0.0)	1 (4.2)	
Current psychotropic medication *n* (%)				
Yes	35 (71.4)	15 (68.2)	14 (58.3)	X^2 = 0.01, *p* =.905
No	14 (28.6)	7 (31.8)	10 (41.7)	
Educational Attainment *n* (%)				
Secondary school	10 (20.4)	6 (24.0)	4 (16.7)	X^2 = 5.26, *p* =.153
College	17 (34.7)	5 (20.0)	12 (50.0)	
University (degree level)	18 (36.8)	12 (48.0)	6 (25.0)	
University (masters or above)	4 (8.1)	2 (8.0)	2 (8.3)	
Comorbid physical health difficulties *n* (%)				
Yes	28 (57.1)	14 (56.0)	14 (58.3)	X^2 = 0.02, *p* =.868
No	21 (42.9)	11 (42.0)	10 (41.7)	
Self-reported problem				
Anxiety	4 (8.2)	1 (12.0)	3 (21.7)	X^2 = 1.28, *p* =.257
Depression	2 (4.1)	0 (0.0)	2 (0.0)	
Both	43 (87.7)	24 (88.0)	20 (78.3)	
Additional mental health problems				
Yes	45 (91.8)	21 (84.0)	24 (100.0)	-
No	4 (8.2)	4 (16.0)	0 (0.0)	
Duration of problem (anxiety and/or depression)				
≤ Two years	9 (18.4)	4 (16.0)	5 (20.8)	X^2 = 0.31, *p* =.855
> Two years < ten years	18 (36.7)	10 (40.0)	8 (33.4)	
≥ Eleven years	22 (44.9)	11 (44.0)	11 (45.8)	

5.2 Attrition

In the ACT group, 12 participants (48%) completed treatment and 13 were lost at post-intervention (52%). Reasons for attrition were: starting college (n = 1), increased caring responsibilities (n = 1) and physical illness (n = 1). The reason was unknown for 10 participants. Participants who dropped out of the intervention did so before the first telephone call (i.e. they could not be contacted) suggesting that the reason for drop-out was not accounted for by therapist variables. In the control group, 15 participants (62.5%) provided completed data and nine (37.5%) were lost at post-intervention (they did not return their questionnaires). There were no significant differences between completers compared to non-completers on any demographic variable or baseline outcome measure.

5.3 Missing data

Accuracy of data entry and coding was achieved by randomly selecting 20% of the data to be checked for errors by the second author (SR). No discrepancies were found. SPSS' Missing Value Analysis showed that the percentage of missing data were 0.95% across the data set. Missing data within variables ranged from 0% - 7.4%, which represents a maximum of two participants failing to provide data on a variable.

Observation of the pattern frequencies graph in SPSS showed that the variable where no missing values were present across all variables was the most common pattern. Analyses of the data was conducted using completed data (n = 27) as well as on an intent-to-treat (ITT) basis (n = 49). The ITT analysis was performed using multiple imputation as the method of replacing missing values with predicted values in order to analyse the complete data set. This identified the distribution of each variable from the complete responses, took five random samples from the distribution samples (as

advocated by Rubin, 1996) and pooled each analysis to provide the final complete data set. Enders (2011) recommends multiple imputation for data missing at random (MAR), which is defined as when missing data may be related to other variables (such as treatment status or previous scores) but missing independently of the unobserved data itself.

5.4 Mixed analysis of variance across outcome measures

Means and standard deviations for each outcome measure are presented in Table 3. Statistical analysis of pre-post data assessed changes in outcomes (QoL, clinical symptoms and processes) over time (baseline and 6 weeks). A series of two-way mixed ANOVAs were conducted. This analysis demonstrated whether outcomes changed differently over time depending on group allocation (a two-way interaction effect analysis).

All analyses met the assumptions of a mixed ANOVA; no outliers, as assessed by examination of studentized residuals for values greater than ±3; normal distribution, as assessed by Normal Q-Q Plots; homogeneity of variances and covariances (p >.05), as assessed by Levene's test and Box's test of equality, respectively. Results from the ITT data are presented below.

Table 3.

Baseline and post-intervention means, standard deviations and ANOVAs for all measures (ITT)

Outcome measure	ACT (n = 25)		Control (n = 24)		Baseline comparison	Interaction effect	Effect size	Main effect time	Effect size	Main effect group	Effect size
	M	*(SD)*	*M*	*(SD)*	(*t*)	*F* (1, 47)	$\eta 2$	*F* (1, 47)	$\eta 2$	*F* (1, 47)	$\eta 2$
Primary outcome											
QoL											
Baseline	73.40	10.42	76.95	9.58	t = -.296, p = .769	2.236 ^{ns}	.045	.476 ^{ns}	.010	.185 ^{ns}	.010
Post-treatment	76.16	9.92	75.94	8.77							
Secondary outcomes											
CORE-34											
Baseline	63.24	17.92	61.75	17.30	t = 1.242, p = .220	.846 ^{ns}	.018	1.613 ^{ns}	.003	.143 ^{ns}	.003
Post-treatment	56.36	15.91	60.65	16.82							
DASS - Depression											
Baseline	20.24	8.39	20.00	7.12	t = -.108, p = .915	.121 ^{ns}	.003	.121 ^{ns}	.003	.005 ^{ns}	.001
Post-treatment	20.24	8.15	20.75	7.79							
DASS - Anxiety											
Baseline	15.92	7.22	15.66	8.82	t = -.110, p = .913	.076 ^{ns}	.002	.004 ^{ns}	.001	.002 ^{ns}	.001
Post-treatment	15.52	4.80	15.91	9.10							
DASS - Stress											
Baseline	19.36	7.25	21.83	5.52	t = 1.338, p = .187	.320 ^{ns}	.007	1.360 ^{ns}	.028	1.680 ^{ns}	.035
Post-treatment	21.28	5.71	22.50	6.57							
Process measures											
AAQ-II											
Baseline	35.56	8.77	36.00	8.54	t = .178, p = .860	.960 ^{ns}	.002	1.464 ^{ns}	.030	.118 ^{ns}	.004
Post-treatment	33.80	6.41	34.95	6.36							

ELS											
Baseline	29.72	11.15	26.29	8.87	t = -1.187, p = .241	1.210 [ns]	.025	3.753 [ns]	.074	.824 [ns]	.017
Post-treatment	31.32	5.04	32.12	7.36							
MAAS											
Baseline	47.56	11.67	47.62	11.65	t = .020, p = .985	.260 [ns]	.001	.381 [ns]	.008	.006 [ns]	.001
Post-treatment	48.80	8.26	48.35	9.82							
CFQ											
Baseline	35.48	7.33	34.50	8.16	t = -.443, p = .660	.792 [ns]	.017	10.62*	.184	.003 [ns]	.001
Post-treatment	31.32	5.04	32.12	7.36							

[ns] = not significant, * significant ($p < .05$), effect size conventions for $\eta 2$ are: small > .01, medium >.06 and large >.14 (Lackens, 2013)

Quality of Life

For the WHOQOL-BREF there was an increase in QoL scores observed between pre-test (M = 73.40, SD = 10.42) and post-test (M = 76.16, SD = 9.92) in the ACT group and a reduction in QoL scores between pre-test (M = 76.95, SD = 9.58) and post-test (M = 75.94, SD = 8.77) in the TAU group. However, these changes were not significant.

AAQ-II

For the AAQ-II there was a small decrease in scores observed between pre-test (M = 35.56, SD = 8.77) and post-test (M = 33.80, SD = 6.41) in the ACT group and a small decrease in scores between pre-test (M = 36.00, SD = 8.54) and post-test (M = 34.95, SD = 6.36) in the TAU group. These changes were not significant.

MAAS

For the MAAS there was an increase in scores observed between pre-test (M = 47.56, SD = 11.67) and post-test (M = 48.80, SD = 8.26) in the ACT group and a reduction in scores between pre-test (M = 47.62, SD = 11.65) and post-test (M = 48.35, SD = 9.82) in the TAU group. These changes were not significant.

CFQ

For the CFQ there was a decrease in scores observed between pre-test (M = 35.48, SD = 7.33) and post-test (M = 31.32, SD = 5.04) in the ACT group and a decrease in scores between pre-test (M = 34.50, SD = 8.16) and post-test (M = 32.12, SD = 7.36) in the TAU group. The main effect of time showed a significant difference in mean outcome scores at different time points, $F(1, 47) = 10.62$, $p = .002$, partial $\eta 2 = .184$, a non-

significant main effect of group, $F(1, 47) = .003$, $p = .960$, partial $\eta 2 = .001$, and no interaction between group and time, $F(1, 47) = 0.792$, $p = .378$, partial $\eta 2 = .017$.

ELS

For the ELS there was a small increase in scores observed between pre-test (M = 29.72, SD = 11.15) and post-test (M = 31.32, SD = 5.04) in the ACT group and an increase in scores between pre-test (M = 26.29, SD = 8.87) and post-test (M = 32.12, SD = 7.36) in the TAU group. These changes were not significant.

CORE-34

For the CORE-34 there was a reduction in scores observed between pre-test (M = 63.24, SD = 17.92) and post-test (M = 56.36, SD = 15.91) in the ACT group and a reduction in scores between pre-test (M = 61.75, SD = 17.30) and post-test (M = 60.65, SD = 16.82) in the TAU group. These changes were not significant.

DASS-21

For the DASS-21 there was a small change across depression, anxiety and stress from baseline to post-intervention. These changes were not significant.

5.5 ITT versus completers analyses

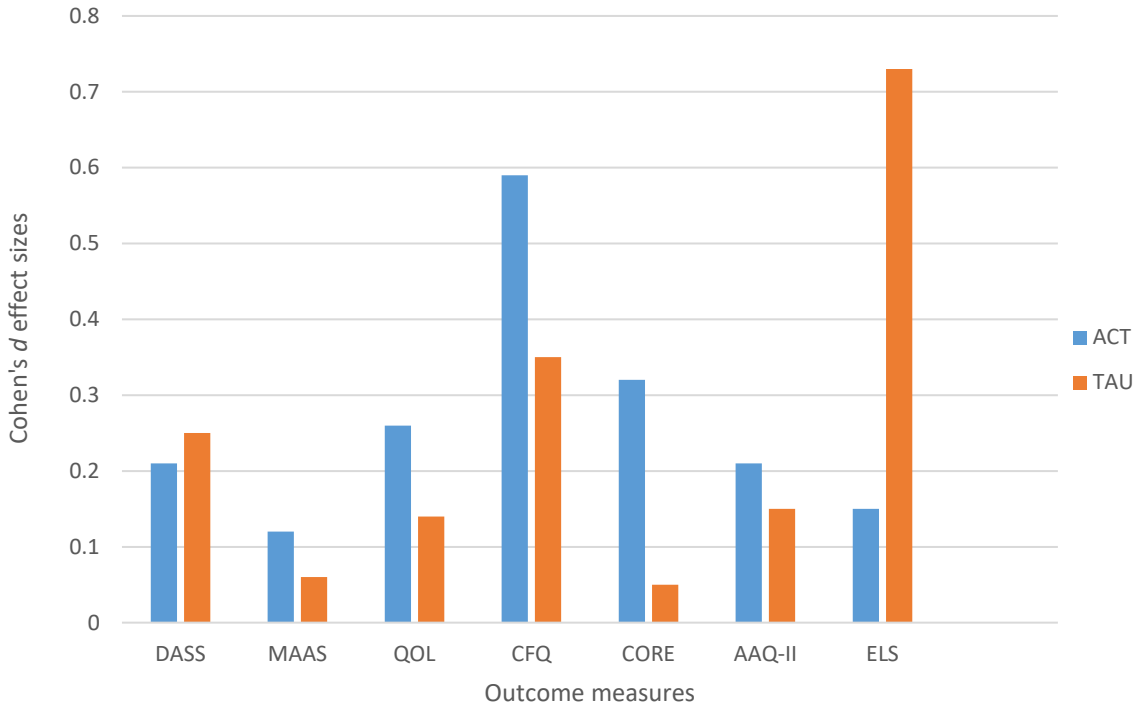
A comparison of the ITT data and completer data revealed similar results, apart from on two measures. There was a significant interaction between intervention and time for QoL (ACT: Mean = 76.25, SD = 14.54; TAU: Mean = 75.60, SD = 11.05, $F(1, 25) = 7.595$, $p = .011$, partial $\eta 2 = .233$), and a significant main effect of time on the ELS,

(ACT: Mean = 31.32, SD = 5.04; TAU: Mean = 32.12, SD = 7.36, $F(1, 25) = 4.671$, $p = .040$, partial $\eta 2 = .157$). Completer data is presented in Appendix 16.

5.6 Within-group effect sizes

Within-group effect sizes were calculated using Cohen's *d.* These were obtained from the mean and standard deviations as well as incorporating the correlation between the two means which is needed to correct for dependence among means (Morris and DeShon, 2002). Effect sizes were calculated and interpreted based on Cohen's (1988) values: small (0.20), medium (0.50) and large (0.80). Results of these can be seen in figure 2. Overall, the ACT group showed larger within-group effects across the majority of outcome measures in comparison to the TAU group. A moderate effect size was found on the CFQ measure ($d = 0.59$) for the ACT group. The remaining effects were small ($d = 0.12$ – $d = 0.32$). For the TAU group, a moderate-to-large effect was found on the ELS ($d = 0.73$). The remaining effects for the TAU were small ($d = 0.05$ – $d = 0.35$).

Figure 2. Within-group effect sizes



5.7 Clinically significant and reliable change

Clinical and reliable change were calculated using the Reliable Change Index (RCI) and Clinical Significance Change (CS) formula (Jacobson & Truax, 1991). Reliable change is equal to the individual's score before the intervention minus the score after the intervention, divided by the standard error of the difference of the test. Criterion A (Jacobson & Truax, 1991; Jacobson, Roberts, Berns, McGlinchey, 1999) indicates that the level of functioning after therapy should fall outside the range of the clinical population (more than 1.96 standard deviations, in the direction of the comparison reference group). Results can be seen in table 4.

Table 4. Clinically significant and reliable change scores across outcome measures

Outcome measure	ACT (n = 25)	Control (n = 24)
QoL		
Recovered (%)	3 (12)	0 (0)
Improved (%)	3 (12)	0 (0)
No change (%)	22 (88)	24 (100)
Deteriorated (%)	0 (0)	0 (0)
MAAS		
Recovered (%)	0 (0)	0 (0)
Improved	3 (12)	4 (16.7)
No change	20 (80)	17 (70.8)
Deteriorated	2 (8)	3 (12.5)
CFQ		
Recovered (%)	8 (32)	3 (12.5)
Improved	8 (32)	3 (12.5)
No change	16 (64)	21 (87.5)
Deteriorated	1 (4)	0 (0)
AAQ-II		
Recovered (%)	3 (12)	0 (0)
Improved	6 (24)	4 (16.7)
No change	18 (72)	17 (70.8)
Deteriorated	1 (4)	3 (12.5)
ELS		
Recovered (%)	6 (24)	12 (50.0)
Improved	6 (24)	12 (50.0)
No change	13 (52)	6 (25.0)
Deteriorated	6 (24)	6 (25.0)
DASS - Depression		
Recovered (%)	5 (20)	1 (4.2)
Improved	5 (20)	2 (8.3)
No change	17 (68)	19 (79.2)
Deteriorated	2 (8)	3 (12.5)
DASS - Anxiety		
Recovered (%)	3 (12)	1 (4.1)
Improved	5 (20)	2 (8.3)
No change	15 (60)	20 (83.4)
Deteriorated	5 (20)	2 (8.3)
DASS - Stress		
Recovered (%)	3 (12)	5 (20.8)
Improved	3 (12)	5 (20.8)
No change	17 (68)	13 (54.2)
Deteriorated	5 (20)	6 (25.0)
CORE		

Recovered (%)	6 (24)	5 (20.8)
Improved	6 (24)	5 (20.8)
No change	17 (68)	16 (66.7)
Deteriorated	2 (8)	3 (12.5)

6.0 Discussion

6.1 Synopsis of findings

The aim of this study was to evaluate an ACT-based GSH intervention, within a clinical sample of individuals with anxiety/depression, in comparison to a non-active control group. The results from this small-scale RCT suggest that GSH did not produce significant results in improving symptoms or QoL, which was opposite to the predicted hypothesis. Within-group effect sizes were small for most outcomes, but generally larger than the comparator. More participants in the ACT group showed reliable and clinical change than those in the TAU group on the QoL, CFQ, AAQ, DASS-depression, DASS-anxiety and the CORE. However, participants in the TAU group also improved, suggesting that the improvement may not have been a result of the intervention itself but some other shared variable. Indeed, depression is a self-limiting condition with natural recovery in around two thirds of patients over one year, but relapsing again within three years (Williams, 1996). Improvement could therefore be partially attributed to spontaneous recovery.

6.2 Comparisons with published literature

The studies by Ritzert et al., (2016) and Fledderous et al., (2012) demonstrated significant improvements on all outcomes. This is in direct contrast to the current

study. This may be due to larger samples (n = 503 and n = 376, respectively) or it could be the result of more comprehensive self-help manuals (for example, a mindfulness CD was included in Ritzert's study). Recruitment strategies also differed; the Ritzert and Fledderous studies used advertising whereas a clinical sample was selected in this study. Indeed, advertised samples have been found to improve more so than within clinical samples (Coull and Morris, 2011). The studies also differ in the length of treatment. The study by Fledderous was nine-weeks and the study by Ritzert was 12 weeks. It may be that extending the intervention length would have allowed participants further time to consolidate and rehearse information. However, this was not possible due to ethical implications of prolonging participant's wait for individual therapy. Participants may have conceivably been more invested in longer interventions. Furthermore, pure self-help interventions have been shown only to be effective with motivated clients (Newman et al., 2011). Motivation may have been an issue.

6.3 Mechanisms and explanations

Further explanations have been postulated as to the reasons for the results of this study. Participants in this sample would have had an expectancy for future treatment. This may have led participants to be less motivated, knowing that more intensive therapy would be offered. Alternatively, participants may have negatively biased their post-treatment outcomes due to the potential worry that improvement may lead to not being accepted for individual therapy. A further explanation is that participants did not improve as expected on the outcomes, perhaps because of their severity or chronicity of difficulties which may have been too severe for a low-intensity

intervention. Indeed, many individuals were excluded at the start of the study due to severity. Clinical samples have been found to be less likely to show improvement (Coull & Morris, 2011).

6.4 Limitations

The main limitation of this study was the low sample size. This may account for the lack of significant differences between the groups, as low sample size reduces statistical power (type II errors) and can also lead to inaccurate estimates of effects. Although several attempts were made to increase sample size such efforts did not provide the required number of participants. The study was also conducted as a doctoral thesis project meaning continuation of participant recruitment until predetermined numbers were met was not feasible. Follow-up was not undertaken. A follow-up allows inspection of treatment longevity. Indeed, Clarke et al. (2004) highlighted increased benefits at follow-up within an ACT group, compared to an active control comparison. Another limitation was that additional treatments, that might have influenced the outcome, were not monitored. However, given participants were on a psychology waiting list it was unlikely that additional treatment would have been sought, especially in such a short period of time. Finally, blinding of participants and therapist was not feasible due to the nature of the conditions. This is a common issue in psychological research (Shean, 2014).

6.5 Implications of study

The generalisability of findings are, to a certain degree, determined by the sample demographics. Participants were predominantly white (96%) and female (67%). The limited ethnoracial diversity may restrict the generalisability of findings.

The study demonstrates that there were no adverse effects and the manual appeared acceptable to participants based on feedback from the telephone calls. A larger scale evaluation of the manual would provide greater confidence in the results.

Practically, this study highlights the difficulties in recruiting from a clinical sample. This may be a result of the severity of the sample, despite recruiting from primary care settings. This intervention may be more suited to milder anxiety/depression, or even as a preventative intervention, reducing the likelihood of developing mental health issues.

6.6 Future directions

Further research could focus on the acceptability of GSH within this population. Qualitative analysis would reveal both individual's reasoning for choosing whether to take part (such as motivational issues, avoidance or personal circumstances) as well their experience utilizing ACT in a GSH format. The use of a follow-up may indicate that change occurs slowly. Indeed, other studies have demonstrated slow longer-term improvement (e.g. Ritzert et al., 2016).

There are several questions that remain unanswered. What is the relative efficacy of ACT-based self-help manuals when compared against each other? What is the relative efficacy of an ACT-based self-help manual in comparison with an established self-help treatment, such as traditional CBT? What is the efficacy of GSH when compared to pure self-help? What is the optimal treatment length of self-help to achieve the greatest improvement in individuals with anxiety/depression? These questions could be addressed in future research.

7.0 Conclusions

GSH for individuals with anxiety/depression was found to provide limited change in symptoms or QoL. This null result may indicate that such sample needs more intensive therapies than GSH. However, the findings need to be interpreted with caution due to the small sample size. Methodological limitations indicate that further research is needed to confirm such results.

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Appendix 1: PRISMA reporting checklist (2009).

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	14
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	14
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	16
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	20
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	21
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	21
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	24
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	24 & Appendix 3
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	25
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	25 & Appendix 4 and 5
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	22
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	30

Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	39
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	26
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	47
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	42
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	28, Flow diagram
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	29
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	30
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	33
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	39
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	n/a
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	45
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	52
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	57
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	62
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	62

Appendix 2: PROSPERO International prospective register of systematic reviews registration document.

UNIVERSITY of York
Centre for Reviews and Dissemination

NHS
National Institute for Health Research

PROSPERO International prospective register of systematic reviews

The clinical effectiveness of group-based interventions using acceptance and commitment therapy for mental health disorders: a systematic review of randomised controlled trials

Shane Ford, David Gillanders, Sally Rankine

Citation

Shane Ford, David Gillanders, Sally Rankine. The clinical effectiveness of group-based interventions using acceptance and commitment therapy for mental health disorders: a systematic review of randomised controlled trials. PROSPERO 2016:CRD42016037140 Available from http://www.crd.york.ac.uk/PROSPERO_REBRANDING/display_record.asp?ID=CRD42016037140

Review question(s)

To investigate the clinical effectiveness of acceptance and commitment therapy delivered in a group-based format for individuals with mental health disorders.

Searches

PsycINFO, MEDLINE, EMBASE and the Cumulative Index to Nursing Allied Health Literature (CINAHL) databases will be searched from their inception to 2016 (estimated month - May).

The search will be performed using the search terms: [‘acceptance and commitment*’ OR 'acceptance*' OR 'third wave' OR 'contextual behavio* science' OR 'third wave' OR '3rd wave'] AND [‘group*’] AND [‘randomi*ed controlled trial’ OR ‘RCT’ OR ‘random*’ OR ‘clinical trial’]. The searches will be conducted in the title, abstract and key word domains.

Additionally, the Association of Contextual Behavioral Science’s (ACBS) own publication database will be searched for additional studies not found in the initial search.

The ACBS's list serve will also be emailed in an attempt to obtain additional information regarding further articles and unpublished articles that meet criteria for this review.

Types of study to be included

Inclusion criteria: Randomised controlled trials

Exclusion criteria: All other study designs (quasi-experimental, controlled trials, uncontrolled trials, case studies etc) will be excluded.

Condition or domain being studied

Common mental health conditions treated within group formats

Participants/ population

Inclusion criteria: Adult participants (18 years or older), any mental health disorder so long as participants score above clinical cut-off at baseline, using a validated measure.

Exclusion criteria: Individuals participating in studies investigating the effects of group-based ACT interventions for physical health conditions, unless the primary outcome of the study focused on mental health conditions within such population.

Intervention(s), exposure(s)

Inclusion criteria: Group interventions using Acceptance and Commitment Therapy, ongoing use of medication that was prescribed before the intervention is deemed appropriate for this review, groups containing three or more

participants, lead by a clinically trained facilitator.

Exclusion criteria: Studies that only incorporate 1-2 components of ACT, such as mindfulness, studies that include two or more individual sessions in addition to a group (individual assessments and debriefs that were not part of the active treatment will be considered), studies that condensed the intervention into one day (e.g. a workshop), mixed interventions that incorporate an additional therapeutic modality that is independent in terms of theory and application to ACT, incorporation of pharmacology as an additional variable to the group itself.

Comparator(s)/ control

Active comparison interventions, as well as control and placebo will be considered.

Context

Inclusion criteria: In order to increase clinical utility, studies with participants in inpatient, outpatient and specialist settings will be included.

Outcome(s)

Primary outcomes

A variety of different clinical outcomes will be considered, depending on the mental health issue being investigated. Studies that use a validated outcome measure of mental health, pre- and post-intervention will be included. Both symptom reduction and functional improvement measures will be reviewed.

Secondary outcomes

None

Data extraction, (selection and coding)

Eligible studies will be extracted via electronic searches. PsycINFO, MEDLINE, EMBASE and the Cumulative Index to Nursing Allied Health Literature (CINAHL) databases will be searched separately. Results will be combined and duplicates will be removed.

The title and abstract of each retrieved study will be sequentially screened. Articles that make no reference to randomisation, group-based therapy, acceptance and commitment therapy or mental health disorders will be excluded. The remaining articles will be read in full until it becomes apparent whether or not they are unrelated to the criteria set for this review.

Bibliographies of obtained articles will be scanned for additional papers. Attempts to contact contributors in the field about ongoing and unpublished work will be made.

Risk of bias (quality) assessment

Full articles will be read by the lead researcher. A proportion of the studies included will also be reviewed independently by another researcher based on established quality criteria. Inter-rater reliability will be calculated. Any discrepancies will be resolved through discussion.

Strategy for data synthesis

A narrative-based synthesis is planned. Quantitative synthesis using an accumulation of effect sizes will be utilised if data is homogeneous enough to conduct such meta-analysis.

Analysis of subgroups or subsets

None planned

Dissemination plans

This review is intended to be published in a peer-reviewed journal. It will be made available through the University of Edinburgh's online thesis database. A copy will be made available on the Association for Contextual Behavioral Science's website (copyright permitting).

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Conflicts of interest
None known

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Country
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Subject indexing assigned by CRD

Subject index terms
Acceptance and Commitment Therapy; Humans; Mental Disorders; Mental Health; Treatment Outcome

Stage of review
Ongoing

Date of registration in PROSPERO
22 April 2016

Date of publication of this revision
22 April 2016

Stage of review at time of this submission	Started	Completed

Preliminary searches	Yes	Yes
Piloting of the study selection process	No	No
Formal screening of search results against eligibility criteria	No	No
Data extraction	No	No
Risk of bias (quality) assessment	No	No
Data analysis	No	No

Appendix 3: Search strategy terms for MEDLINE

Search strategy: MEDLINE

01. acceptance and commitment*
02. acceptance*
03. ACT
04. 3rd Wave
05. third wave
06. contextual behavio* science
07. 1 or 2 or 3 or 4 or 5 or 6
08. group*
09. randomi*ed controlled trial
10. RCT
11. random*
12. clinical trial
13. 9 or 10 or 11 or 12
14. 7 and 8 and 13

Appendix 4. Example template Data Extraction Tables, modified from the Cochrane Public Health Group Data 'Extraction and Assessment Template' (Cochrane Public Health Group, 2011).

Study and date

General Information		
Date completed	Data Extractor:	
First Author:	Year of study:	
Citation:		
Publication type: Journal Article ☐ Abstract ☐ Other (e.g. Book Chapter) ☐ _____		
Written in English ☐		

Study Characteristics			Page
Methods	Study design Recruitment Unit of randomisation Unit of analysis		
Participants	Age range Mean age (SD) Gender (female) Race/Ethnicity Country Setting Clinical condition Diagnostic criteria Sample size calculation Sample size (initial/completed) Exclusion criteria		
Intervention	Aims of study Group 1 (G1) G1 Treatment components G1 Facilitator(s) *(training & supervision)* Group 2 (G2) G2 Treatment components G2 Facilitator(s) *(training & supervision)* Additional factors		
Outcomes	Measures Vailed & Reliable? ☐ Outcome time points	Effect sizes	
Results	Statistical method used Main findings		
Notes			

Appendix 5: Modified Effective Public Health Practice Project's 'Quality Assessment Tool for Quantitative Studies' with marking criteria.

Component	Question	Score	Description	Rating
Selection Bias	(Q1) Are the individuals selected to participate in the study likely to be representative of the target population?	1) Very likely 2) Somewhat likely 3) Not likely 4) Can't tell	1) Randomly selected from a comprehensive list of individuals in the target population 2) Referred from a source e.g. clinic) in a systematic manner 3) Self-referred	**STRONG** – Very likely (Q1 is 1) and 80% or more participation (Q2 is 1) **MODERATE –** Somewhat likely (Q1 is 1 or 2) and 60 – 79% participation (Q2 is 2) or can't tell (Q2 is 5) **WEAK –** Not likely (Q1 is 3) or there is less than 60% participation (Q2 is 3) or selection is not described (Q1 is 4) and participation is not described (Q2 is 5)
	(Q2) What percentage of selected individuals agreed to participate?	1) 80 - 100% 2) 60 – 79% 3) Less than 60% 4) Not applicable 5) Can't tell		
Study Design	Indicate the study design	1. RCT 2. Controlled clinical trial 3. Cohort analytic 4. Case-control 5. Cohort 6. Interrupted time series 7. Other		**STRONG** – Assigned to articles that describe RCTs and CCTs **MODERATE –** Describe cohort analytic studies, case control study, cohort designs or

		8. Can't tell		interrupted time series
	Was the study described as randomised?	Yes No		**WEAK –** Assigned to articles that used any other method or did not state the method used.
	If yes, was the method of randomisation described?*	Yes No	Score no if authors report a method (e.g. alternation, case numbers, dates of birth, day of the week) which is not truly random	
	If yes, was the method appropriate?*	Yes No	Score no if the randomised sequence is open to those recruiting, allocating or providing the intervention	
*A score of no downgrades the study to a controlled clinical trial				
Confounders	(Q1) Were there important differences between groups prior to the intervention?	1) Yes 2) No 3) Can't tell		**STRONG** – Assigned to articles that controlled for at least 80% of relevant confounders (Q1 is 2, **OR** Q2 is 1).
	Example confounders	1. Race 2. Sex 3. Marital status/family 4. Age 5. SES 6. Education 7. Health status		**MODERATE –** Assigned to articles that controlled for at 60 - 79% of relevant confounders (Q1 is 1 **AND** Q2 is 2). **WEAK –** Assigned to articles that

		8. Pre-intervention score on outcome measure		controlled for less than 60% of relevant confounders (Q1 is 1 **AND Q**2 is 3, **OR** control of confounders was not described (Q1 is 3 **AND** Q2 is 4).
	(Q2) If yes, indicate the percentage of relevant confounders that were controlled (either in the design (e.g. stratification, matching or analysis)	1) 80 – 100% (most) 2) 60 – 79% (some) 3) Less than 60% (few or none) 4) Can't tell		
Blinding	(Q1) Was (were) the outcome assessor(s) aware of the intervention or exposure status of participants?	1) Yes 2) No 3) Can't tell		**STRONG** – Outcome assessor not aware and study participants not aware (Q1 and Q2 are 2)
	(Q2) Were the study participant is aware of the research question?	1) Yes 2) No 3) Can't tell		**MODERATE –** Outcome assessor not aware (Q1 is 2) or study participants not aware (Q2 is 2) or blinding not described (Q1 and Q2 are 3) **WEAK –** Outcome assessor is aware (Q1 is 1) and study participants are aware (Q2 is 1)
Data Collection Methods	(Q1) Were data collection tools shown to be valid?	1) Yes 2) No 3) Can't tell	If 'face' validity or 'content' validity has been demonstrated,	**STRONG** – Valid and reliable data collection tools (Q1 and Q2 are 1)

	(Q2) Were data collection tools shown to be reliable?	1) Yes 2) No 3) Can't tell	this is acceptable Score yes if standard assessment tools have known reliability and validity from a separate study	**MODERATE –** The data collection tools have been shown to be valid (Q1 is 1); **and** the data collection tools have not been shown to be reliable (Q2 is 2) **or** reliability is not described (Q2 is 3). **WEAK –** The data collection tools have not been shown to be valid (Q1 is 2) **or** both reliability and validity are not described (Q1 is 3 and Q2 is 3)
Withdrawals and Drop-outs	(Q1) Were withdrawals and drop-outs reported in terms of numbers and/or reasons per group? (Q2) Indicate the percentage of participants completing the study. (If percentage differs by groups, record the lowest)	1) Yes 2) No 3) Can't tell 4) Not applicable 1) 80 – 100% 2) 60 - 79% 3) Less than 60% 4) Can't tell 5) Not applicable (i.e. retrospective case-control)	Score yes if both numbers and reasons stated % of subjects remaining in the study at the final data collection period	**STRONG** – will be assigned when the follow-up rate is 80% or greater (Q2 is 1). **MORDERATE –** will be assigned when the follow-up rate is 60 – 79% (Q2 is 2) **OR** Q2 is 5 (N/A). **WEAK –** will be assigned when a follow-up rate is less than 60% (Q2 is 3) or if the withdrawals and drop-outs were not described (Q2 is 4).
		1) 80 – 100%		

Intervention Integrity	(Q1) What percentage of participants received the allocated intervention or exposure of interest?	2) 60 - 79% 3) Less than 60% 4) Can't tell		**STRONG** – will be assigned when the percentage receiving the allocated intervention is 80% or greater (Q1 is 1), Q2 & Q4 are yes and Q3 is no.
	(Q2) Was the consistency of the intervention measured?	1) Yes 2) No 3) Can't tell	The method of measuring that the intervention was provided to all participants in the same way is described	**MODERATE –** Will be assigned when the percentage receiving the allocated intervention is 60-79% (Q1 is 2) **AND** Q2 & Q3 are no **AND** Q4 is yes.
	(Q3) Is it likely that subjects received an unintended intervention (contamination or co-intervention) that may influence the results?	1) Yes 2) No 3) Can't tell		**WEAK –** will be assigned when the percentage receiving the allocated intervention is less than 60% (Q1 is 3) or if the withdrawals and drop outs were not described (Q1 is 4) **AND** Q2 & Q4 are no or can't tell **AND** Q3 is yes or cannot tell.
	(Q4) Are the core components of the intervention implemented within the intervention?	1) Yes 2) No 3) Can't tell	The core components of the intervention are described or referenced from existing protocols	
Analysis	(Q1) Indicate the unit of allocation (circle one)	Community Organisation/ Institution		**STRONG –** will be assigned when

		Practice/Office Individual		Q3, Q4 & Q5 are yes.
	(Q2) Indicate the unit of analysis (circle one)	Community Organisation/ Institution Practice/Office Individual		**MODERATE –** will be assigned when Q3 & Q4 are yes, but Q5 is no.
	(Q3) Are the statistical methods appropriate for the study design?	1) Yes 2) No 3) Can't tell		**WEAK –** will be assigned when Q3, Q4 and Q5 are no or cannot tell.
	(Q4) Is the analysis performed by the intervention allocation status (i.e. intention to treat rather than the actual intervention received?)	1) Yes 2) No 3) Can't tell		
	(Q5) Power calculations reported and sufficient power achieved	1) Yes 2) No 3) Can't tell	Score no if power calculation reported but not achieved	

Global Rating for this Paper:

STRONG – no WEAK ratings
MODERATE – one WEAK rating
WEAK – two or more WEAK ratings

Based on the EPHPP's Quality Assessment Tool for Quantitative Studies dictionary which can be downloaded from: http://www.ephpp.ca/PDF/QADictionary_dec2009.pdf

Appendix 6: The Journal of Contextual Behavioral Sciences' *Guide for Authors*.

JOURNAL OF CONTEXTUAL BEHAVIORAL SCIENCE

ELSEVIER

AUTHOR INFORMATION PACK

TABLE OF CONTENTS

ISSN: 2212-1447

DESCRIPTION

The *Journal of Contextual Behavioral Science* is the official journal of the Association for Contextual Behavioral Science (ACBS).

Contextual Behavioral Science is a **systematic and pragmatic approach** to the understanding of behavior, the solution of human problems, and the promotion of human growth and development. Contextual Behavioral Science uses **functional principles and theories** to analyze and modify action embedded in its historical and situational context. The goal is to **predict and influence behavior**, with precision, scope, and depth, across all behavioral domains and all levels of analysis, so as to help create a behavioral science that is more adequate to the challenge of the human condition.

Contextual behavioral science is a strategic approach to the analysis of human behavior that proposes the need for a **multi-level** (e.g. social factors, neurological factors, behavioral factors) and **multi-method** (e.g., time series analyses, cross-sectional, experimental) exploration of **contextual and manipulable** variables relevant to the prediction and influence of human behavior.

The journal considers papers relevant to a contextual behavioral approach including: Empirical studies (without topical restriction - e.g., clinical psychology, psychopathology, education, organizational psychology, etc.) Brief reports on preliminary, but provocative findings Reviews (systematic reviews and meta-analyses are preferred) and Conceptual and philosophical papers on contextual behavioral science

We are particularly interested in: Papers emphasizing the study of core **behavioral processes** that are relevant to a **broad range of human problems** Papers **bridging different approaches** (e.g., connecting behavioral approaches with cognitive views; or neurocognitive psychology; or evolutionary science) Papers that **challenge** a contextual behavioral science approach from an informed perspective

The journal welcomes papers written by researchers, practitioners, and theoreticians from different intellectual traditions. What is distinctive is not a narrowly defined theory or set of applied methods but whether the methodology, conceptualization, or strategy employed is relevant to a contextual behavioral approach.

Special Issues

The Journal welcomes suggestions for Special Issues. Proposals for a themed Special Issue should be sent to the Editor-in-Chief, Emily Sandoz at emilysandoz@louisiana.edu, and should include suggested Executive, Advisory or Guest Editors, a proposed call-for-papers, 6-10 provisional authors and topics (specific titles or general areas), a proposed timeline for submission, peer-reviewing, revision and publication. All manuscripts in a special issue will be subject to the normal process of peer-review.

ABSTRACTING AND INDEXING

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EDITORIAL BOARD

GUIDE FOR AUTHORS

Types of article

All manuscripts must clearly and explicitly be of relevance to CBS. You may find the JCBS article "Contextual Behavioral Science: creating a science more adequate to the challenge of the human condition" helpful in assessing whether your manuscript is likely to be of interest to readers of this journal.

Articles should fall into one of seven categories:
1. Empirical research (up to 6000 words)
2. Brief empirical reports (up to 3000 words)
3. Review articles (up to 10,000 words)
4. Conceptual articles (up to 6000 words)
5. In practice (up to 3000 words)
6. Practical innovations (up to 3000 words)
7. Professional interest briefs (up to 3000 words)

Word limits exclude references, tables and figures but include the abstract

1. Empirical research. JCBS welcomes manuscripts across a breadth of domains from basic behavioral science to clinical trials. Research concerning the measurement and testing of process of change is particularly welcome. Potential methodologies include but are not limited to: randomized controlled trials, single case experimental designs, cross-sectional and prospective cohort studies, mixed-methods designs, small scale analog studies. Papers reporting null findings are also welcome if their methodology is sound and their power sufficient. Authors of such papers will need to emphasize the implications of their findings for future research and practice.

2. Brief empirical reports. Manuscripts in this section may report preliminary, provocative or replicated results. Empirically sound methodology and adequate power remain important considerations.

3. Review articles. Manuscripts reviewing a wide range of topics are encouraged as long as their content is directly relevant to CBS. Systematic reviews and meta-analyses are particularly welcome. Authors are advised to consult relevant MARS (http://www.apa.org/pubs/authors/jars.pdf) and PRISMA resources (http://www.prisma-statement.org/) when preparing such manuscripts.

4. Conceptual articles. Manuscripts in this section should address conceptual or theoretical issues relevant to CBS. This may include papers that discuss relevant philosophical assumptions and traditions, or conceptual papers which explore aspects of or inconsistencies in contextual behavioral theory and science.

5. In practice. Manuscripts in this section are designed to make CBS useful to practitioners from a wide variety of areas. Manuscripts must be written in an accessible style and should be easily understood by practitioners who are not experts in research or basic behavioral science. Manuscripts should provide both clear insights for new practitioners as well as stating the questions that remain to be answered by future research.

6. Practical innovations. Manuscripts in this section seek to apply the findings and applications of CBS to under-studied, under-served or novel areas. The scope of these manuscripts is limited only by the journal's broad mission: creating a science more adequate to the challenge of the human condition.

7. Professional interest briefs. Manuscripts in this section highlight professional issues of relevance to those working in the field of CBS. Examples include manuscripts related to training and supervision, assessment methods in professional settings or opinions on contemporary issues.

The Journal welcomes suggestions for Special Issues. Proposals for a themed Special Issue should be sent to the Editor-in-Chief, Emily Sandoz at emilysandoz@louisiana.edu, and should include suggested Executive, Advisory or Guest Editors, a proposed call-for-papers, 6-10 provisional authors and topics (specific titles or general areas), a proposed timeline for submission, peer-reviewing, revision and publication. All manuscripts in a special issue will be subject to the normal process of peer-review.

Contact details for submission

To contact the Editor-in-Chief prior to your submission with any questions, please email emilysandoz@louisiana.edu

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BEFORE YOU BEGIN

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Reference to a chapter in an edited book:
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Cancer Research UK. Cancer statistics reports for the UK. (2003). http://www.cancerresearchuk.org/aboutcancer/statistics/cancerstatsreport/ Accessed 13.03.03.
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Appendix 7: Thesis Research Protocol.

Thesis Research Protocol

Provisional Thesis Title:

Evaluating Acceptance and Commitment Therapy (ACT) as a Low-Intensity, Manual-Based, Guided Self-Help Intervention for Anxiety and Depression: A Pilot Study.

Principal Investigator/Researcher

Mr Shane Ford*, Trainee Clinical Psychologist (Five Year Specialist Route), Full-time employed within NHS Forth Valley & Full-time student at the University of Edinburgh (completing a Doctorate in Clinical Psychology).

Allocated Thesis Project Supervisors

Clinical **Dr Sally Rankine, Consultant Clinical Psychologist, Head of Adult Psychology Services, Forth Valley NHS.**

Academic 1 **Dr David Gillanders*, Academic Director of Studies, University of Edinburgh**

Proposed setting(s): **NHS Forth Valley, Adult Psychology Services (Falkirk & Stirling Community Hospitals)**

Anticipated Month & Year of Submission of Thesis: 1st May 2017

Version (date): V4_17.04.2016

*Protocol Authors

List of Abbreviations

ACT – Acceptance and Commitment Therapy
CBT – Cognitive-Behavioural Therapy
RCT – Randomised Controlled Trial
NICE – National Institute for Clinical Excellence
GSH – Guided Self-Help

Introduction

1. Acceptance and Commitment Therapy

Acceptance and Commitment Therapy (ACT) is an empirically based psychological intervention which has a strong theoretical framework based on Relational Frame Theory (RFT; See Blackledge, 2003, for an overview). Its philosophical roots are pragmatic and are grounded in functional contextualism (Hayes, Strosahl & Wilson, 1999). The goal of ACT is to increase psychological flexibility (Hayes, Luoma, Bond, Masuda & Lillis, 2006). Psychological flexibility can be defined as 'the ability to contact the present moment more fully as a conscious human being, and to change or persist in behavior when doing so serves valued ends', (Hayes, Strosahl, Bunting, Twohig & Wilson, 2004, p.5). It achieves this by focussing on six principles (acceptance, defusion, self-as-context, values, being present and committed action) which are theoretically linked to RFT (Hayes et al., 1999). Since 1986 there have been over 100 ACT-based randomised controlled trails (RCT), half of which appeared after 2009 (Association of Contextual Behavioural Science; ACBS, 2014). These studies indicate that ACT is associated with consistent large effects when compared to wait-list or inactive controls across a broad spectrum of disorders including depression (Bohlmeijer, Fledderus, Rokx & Pieterse, 2011), social anxiety (Dalrymple & Herbert, 2007), panic disorder (Meuret, Twohig, Rosenfield, Hayes, & Craske, 2012) and obsessive-compulsive disorder (Twohig et al., 2010).

2. Guided Self-Help

For many clients, guided self-help (GSH) is the first point of call when treating anxiety/depression. For both these disorders, the National Institute for Clinical Excellence (NICE; 2009, 2011) and the Matrix (National Education for Scotland, 2011) recommend Cognitive-Behavioural Therapy-based GSH interventions for individuals presenting with mild-moderate symptoms. NICE reviewed a total of ten RCTs using Cognitive-Behavioural Therapy-based GSH for depression (NICE, 2009). They concluded that five of the studies showed a large effect in reducing

depressive symptoms when compared to controls. Four RCTs were reviewed for generalised and mixed anxiety disorder. It was concluded that there was a small-moderate improvement (NICE, 2011). However these studies could not be analysed together due to their heterogeneity. NICE also reported that the quality of this evidence was low. Despite such critique, Cognitive-Behavioural Therapy-based GSH remains the recommend treatment of choice for mild anxiety.

Furthermore, a meta-analysis investigating the effectiveness of Cognitive-Behavioural Therapy-based GSH interventions for anxiety and depression concluded that such interventions were less effective in clinical samples, compared to samples recruited via advertisements (Coull & Morris, 2011). Further research to investigate the effectiveness of Cognitive-Behavioural Therapy-based GSH in clinical samples is warranted, as it is these individuals who would typically present to their GP or mental health services.

Cavanagh, Strauss, Forder & Jones (2014) suggest that, due to the success of Cognitive-Behavioural Therapy-based self-help interventions, such results may extend to acceptance-based self-help. Indeed, self-help studies using ACT have found positive results for smoking cessation (web-based; Bricker, Wyszynski, Comstock & Heffner, 2013), depression (web-based; Carlbring, 2013, Fledderus, Bohlmeijer, Pieterse & Schreurs, 2012, Meyer et al., 2009), chronic pain (web-based; Buhrman 2013, Johnston, Foster, Shennan, Starkey and Johnson, 2010 and manualised; Thorsell, 2011), and tinnitus (web-based; Hesser et al., 2012). A recent meta-analysis identified 15 RCTs that used acceptance-based and/or mindfulness-based components within a self-help context (Cavanagh et al., 2014). It revealed small-medium effect sizes with a significant reduction in anxiety/depression compared to controls. However, only seven of the reviewed studies were ‘pure’ ACT-based interventions, with the remaining eight consisting of mindfulness components. Additionally, self-help and guided self-help studies were combined. Coul and Morris (2011) argue that GSH can be regarded as a more intensive treatment, with therapist input impacting on the effectiveness of the outcome. Therefore, although this meta-analysis highlights that ACT-based approaches are

promising, further research needs to delineate self-help and GSH as well as reviewing 'pure' ACT interventions. As such, another aim of the proposed study is to investigate the effectiveness of using pure ACT-based GSH interventions.

3. The Proposed Study

Given the above evidence, further research is needed to explore an ACT approach in a self-help context. If successful it will highlight that ACT-based GSH is another possible delivery method for GSH interventions. The inclusion of a non-active control will enable a comparison between the intervention and receiving no treatment. Demonstrating the effectiveness of a particular model means identifying which processes they achieve their outcomes. Mediation analysis will demonstrate whether ACT derived its outcome through the process of psychological flexibility. This will have strong implications with regards to patient choice; offering an alternative low-intensity intervention to patients.

Research Questions / Objectives:

1) The principal research question / objective

1. Does receiving a six week intervention, in the form of an ACT-based GSH manual with minimal telephone support, increase the quality of life for participants with anxiety and/or depression, within a primary care mental health setting?

   Hypothesis 1: Receiving a 6-week intervention, in the form of an ACT-based GSH intervention with minimal telephone support, will significantly increase quality of life in participants with anxiety and/or depression within a primary care mental health setting, compared to controls.

2) The secondary research question / objective.

1. To investigate whether increases in psychological flexibility (the ability to make contact with the present moment and to change or persist in behaviour that serves an individual's values) will mediate (provide a causal relationship between) the intervention and improved quality of life.

   Hypothesis 2: Psyhchological flexibility will mediate the relationship between anxiety/depression, psychological distress and quality of life within the ACT intervention.

Methodology

Design:

An experimental, multi-arm parallel, randomised design will be used. This comparison study will have two groups: the intervention group, who will receive the ACT self-help manual as well as two phone calls from the principal investigator, and the wait-list as usual group who will continue to wait for individual treatment on the Primary Care Adult Psychology waiting list, without receiving the self-help manual or phone calls. The wait-list as usual group will act as the control arm to which data can be compared to see whether the intervention provided any benefit.

Participants:

A total of 52 participants will be needed to reach statistical power within this study (26 participants in each group; see sample size calculations below). To achieve this it is estimated 208 patients will need to be invited to take part in the study (considering a conservative 25% uptake, n=52, and an estimated 30% drop out rate, n=12). Participants will be recruited from the Forth Valley Primary Care Clinical Psychology waiting list. Inclusion into the study will be based on the criteria mentioned below.

Methodology:

Patients are referred into Primary Care Adult Psychology Services for individual therapy from their GP/Health Care Professional. This referral is usually due to a diagnosis of or symptoms suggesting

mild to moderate anxiety and/or depression. The waiting list is split across two geographical locations, 11 miles apart within the central belt of Scotland. The patient's referral letters from the GP are screened within a departmental referral meeting and those who are suitable for the service (to receive one-to-one therapy) are sent an opt-in letter by the department. This letter from the service will include the below paragraph:

'The department is continually looking for ways to enhance its service. We are currently involved in a piece of research investigating the effects of self-help material on improved quality of life. You may be suitable to participate in this study whilst on our waiting list and you may be sent information about the study and invited to take part. Please be assured that the researcher is a member of our team and your details have not been passed to anyone else. The service we offer you will not be effected in any way whether you take part of not.'

This will be classed as the 'first point of contact' by the department which introduces the patient to the research.

The opt-in letter asks the patient to contact the department via telephone should they wish to be added to the department's waiting list for individual therapy. If a patient states that they do not wish to be contacted regarding the study when they opt-in for individual therapy (their usual care) the admin team will make a note of this and pass it on to the Principal Investigator. Similarly, a patient may ring the department at any other time to state that they do not wish to be contact with regards to the research. This will again be passed on to the researcher.

Those who do opt-in for individual therapy will be added to the departmental waiting list. Their referral letter will then be screened by the Principal Investigator for suitability for this study. Those that meet exclusion/inclusion criteria for the study will be sent information in the post inviting them to take part. This will include the study's participant information sheet, and a consent form and questionnaires should they wish to participate. The participant information sheet will also contain contact numbers for the Principal Researcher and the Clinical Supervisor should patients wish to

discuss any aspect of the study further before consenting. A contact number for the Head of Psychology Services within Forth Valley will also be given and they will act as a contact independent of the study, should patients wish to speak about participating in research in general.

Those that sign the consent form will be asked to complete the questionnaires and return both in a FREEPOST envelope to the department. They will then be opened by the Principal Investigator.

A summary of how participants will be recruited into the study as described above is shown below:

1) The patient's GP refers the patient for therapy by letter to the Primary Care Adult Psychology Service

2) The GPs referral letter is screened for suitability within the service's referral meeting by the department

3) Those appropriate for individual therapy within the service are sent a letter from the department asking them to opt-in to be put on the waiting list for individual therapy (this letter will contain the above paragraph stating the department is participating in a piece of research that the patient may be suitable for and will be contacted in due course)

4) Those who have opted in to the service are placed on the service’s waiting list

5) The Principal Investigator will go through the waiting list and screen for those suitable for the study

6) Those who are suitable will be sent out a participant information sheet, consent form and questionnaires in the post

7) Those that sign and return their consent form as well as the questionnaires will be assigned to the study

Those who are deemed suitable based on the inclusion/exclusion criteria will be randomly assigned to either the acceptance and commitment intervention (experimental group 1), or to the control

group. This will be done using an online randomiser: http://www.randomizer.org/. Randomisation will be done equally across the two locations by groups of participants (e.g. the first 8 participants will be randomly allocated so that each condition is balanced across recruitment). As this intervention (experimental group 1) cannot be considered an effective treatment until analysis of the data has been completed, participants in the control group will not receive the manual after the intervention (as with a wait-list control group design). They will continue to wait on the department's waiting list for individual therapy, which would be their 'usual treatment'.

If a participant is called for their usual treatment (e.g. individual therapy within Primary Care Adult Psychology Services) whilst still within this study, their participation within the study will stop prematurely. This is unlikely to happen as the department's waiting times have been carefully observed over the past 4 years; the waiting time has not dropped below 8 weeks (which is the time needed for participation in this study) during this period. However, potential participants will be made aware of this in the Participant Information Sheet.

Participants who have been assigned to the intervention group will be sent the self-help manual with instructions to read one chapter each week for a period of six weeks. Participants will be told the rationale of only reading one chapter each week (to allow time to practice the experiential exercises and reflect back on the chapter so that information is retained). A week's leeway will be given with regards to completing a chapter each week as it is understandable that participants may have other commitments such as a holiday during the intervention. Adherence to the manual will be assessed using a self-report adherence measure which will ask participants to identify what page they reach each week and how many of the weekly tasks they have completed. This information will also be checked during the two telephone calls as described below.

The development and content of the treatment manuals are summarised at the end.

The researcher will make two telephone calls to the participants in the intervention group to provide basic support during weeks two and five. The same set of questions will be asked to each participant

and the length of the calls will be recorded so that 'outliers' (phone calls that over-exceed or under-exceed 10-15 minutes) can be taken into consideration during the analysis.

After six weeks, all participants (the experimental group and control group) will receive the same set questionnaires via post that they were asked to complete at the beginning of the intervention.

A limitation of this study will be that neither participants nor the investigator will be blinded to the allocated groups during the study. This is because participants will be actively participating in the intervention and will therefore know which condition they have been assigned to based on whether they receive the manual or not. The investigator will also act as the individual providing telephone support and will therefore be aware of those who are allocated to the intervention group. Several steps have been put in place to ensure any researcher effects or bias are limited. For example, the researcher will be blind to the allocation sequence until consent has been taken. Therefore the researcher will be unaware of which condition each participant will be allocated to during the recruitment phase. The researcher will then have no further contact with those in the control group. Set scripts will be used by the principal researcher during the telephone calls to those in the intervention group to make sure similar questions are being asked to each participant. As the researcher is part of the guided self-help intervention itself, their influence during the telephone calls will be considered part of the outcome. Self-report measures will be used, providing an objective source of data for evaluation of outcomes.

The researcher will also fulfil the role of the data collector.

Analysis of the data will be conducted using SPSS software on an NHS computer and password protected within the researchers work account.

The development of the treatment manual:

The content of the ACT manual is primarily based on the underlying theory of the model as outlined in Hayes, Strosahl, and Wilson (1999). Strategies, metaphors and examples were influenced by key self-help publications which are referenced within the manual.

The manual was distributed to 10 individuals who agreed to proof-read and provide feedback on readability and clarity. This feedback was taken on board and the manual was amended accordingly. The individuals consisted of a mix of professionals, clinical psychology students and individuals with no prior knowledge of psychology or therapy.

1) Expertise:

The ACT manual was written by the lead researcher – a Doctoral level student completing their training in Clinical Psychology at the University of Edinburgh. It was then edited by Dr David Gillanders, Academic Director of Studies, University of Edinburgh. Dr Gillanders is an international ACT expert and has published and taught ACT-based materials for many years.

2) Accessibility:

Every effort has been made to make the treatment manual accessible to a wide audience. The manual has six chapters, which contains pictures, drawings and diagrams and has a strong design layout. The tone of language is empathetic and non-judgemental. Case studies and examples are used throughout the manual to demonstrate key aspects of the therapy.

The manuals were formatted in a way that was accessible to the majority of readers. For example, medium text size was used; clear font style and illustrations were incorporated to aid learning. Chapters are less than six pages each meaning most participants will be able to sustain concentration. Black ink on white paper was utilised making reading easy. Every effort will be taken to provide alternative formats of the manuals, including large text and alternative coloured backgrounds should this be required by the participants.

3) Reading age:

A sample of text from the manual was taken to assess readability. Using a readability calculator (www.readabilityformulas.com), the following results were obtained:

Table 3. Readability scores based on seven frequently used formulas.

Readability Formula	ACT Manual
Flesch Reading Ease score	69.6 – Fairly easy to read
Gunning Fog	12.5 – Hard to read
Flesch-Kincaid Grade Level	8.8 – Ninth grade
The Coleman-Liau Index	7 – Seventh grade
The SMOG Index	8.5 - Ninth grade
Automated Readability Index	9.2 - 13-15 - years old
Linsear Write Formula	12.8 - College

The consensus, based on the above 8 readability formulas produced a grade level of 9, for the ACT manual, which is classed as 'fairly easy to read' and suitable for 13-15 years old. It is therefore predicted that the manual is at a suitable readability level for the participant sample.

4) Manual Content:

A summary of the content within each of the chapters: ACT manual.

Week 1

How to use the manual. What is ACT? What have you tried so far? Creative hopelessness. Case Study. Internal & External struggles. Amplifying Suffering through control. Willingness. Metaphors used: Quicksand & Sailing Boat. Monitoring difficult thoughts, feelings and sensations. Thinking about how much effort was put into making these go away. Recording the effects of such efforts

Week 2

Avoidance & giving up the struggle. Why we get stuck and healthy distancing. Strategies that allow flexibility. Case study. Flexibility in attending to thoughts. Metaphors used: Tug of war with a monster & Hands as thoughts. Using suggested strategies and recording which ones worked well for which contexts.

Week 3

Self-as-context. The story of you. Another kind of self. Perspective shifting and connecting with the noticing you. Metaphors used: Rugby pitch (formally the Chess Board metaphor)Taking an observing stance towards thoughts, feelings and sensations.

Week 4

Mindfulness. Simply noticing. Case study. Staying connected. Mindfulness exercises: 5 senses, passing thoughts, mindfulness of the body. Practicing being present. Mindfulness practice sheet to be filled in which reflects on the benefits and difficulties.

Week 5

Values. Direction of living. Becoming aware of what you value. My values. What am I willing to have to move in the direction of my values? Case study. Creating value cards based on different domains (e.g. education, leisure, family, relationships etc.).

Week 6

Taking action. Goals. What is holding you back? Case study. Problem solving. Strategies to help aid action. Developing short, medium and long-term goals in the direction of personal values.

Week 7

Conclusions. Where do we go from here? A summary of the core principles. Useful resources. Sources of additional help.

The principal inclusion and exclusion criteria

Inclusion Criteria:

- 18 – 65 years old
- On the primary care waiting list for individual therapy
- Anxiety or depression/low mood as indicated from the referral letter. Once contacted, the client's severity of anxiety/depression will then be assessed formally using the Depression, Anxiety and Stress Scales (DASS-21). Those with mild to moderate (≥ 4 and ≤ 7) mixed anxiety (including panic, agoraphobia, OCD, GAD and phobias) or depressive/low mood (including dysthymia; ≥ 5 and ≤ 10) will be included. For those participants presenting with both anxiety and depression, at least one must reach the minimum cut off score and neither should exceed the maximum cut-off score. Those with severe depression will not be included within the trial and their GP will be informed as this could pose a potential risk to their wellbeing. *[For ease of viewing, the above paragraph, highlighted, forms part of version 3's protocol and will be **REMOVED** as inclusion criteria in this version (4)]*
- Adequate English language ability
- Able to give informed consent

Exclusion Criteria:

- High suicide risk (as indicated with a risk score of >0.3 on the Clinical Outcomes in Routine Evaluation questionnaire; CORE-34)*
- Participants that have been flagged at the referral meeting to receive specialised individual therapy (e.g. schema-focussed therapy)
- Medication change within the last three months**
- Currently receiving or received psychological help within the last 6 months using a CBT or ACT modality (e.g. Beating the Blues, Anxiety Management Groups, Mindfulness, Individual therapy)

- Currently taking part in another research study
- Intellectual impairment (e.g. a learning disability)
- Referral for a primary diagnosis, other than anxiety/depression, that would significantly overarch any work focussing on anxiety/depression even if the above criteria is met for anxiety/depression (e.g. an eating disorder whereby the stated symptoms: cognitions, physical sensations, emotions and behaviours, are orientated solely around food).

* High suicide risk would usually be flagged and managed before a referral into the Psychology Department (as it is a primary care service). However, if it is highlighted on the CORE standardised measure appropriate steps will be taken by the principal investigator to signpost such individual to the relevant service (e.g. Intensive Home Treatment Team).

**Those individuals who have started or changed medication within the last 3 months will still be eligible to participate, but will be put on hold until this time period has elapsed. They will be informed of this and told that they may not be entered into the trial if recruitment targets are met or individual treatment becomes available (the waiting list will be reviewed at the time).

Data Collection

The data will be collected through 8 self-report standardised questionnaires as described below:

1. Clinical Outcomes in Routine Evaluation (CORE; Barkham et al., 1998)

The *Clinical Outcomes in Routine Evaluation Outcome Measure* (CORE-OM) is a 34-item self-report questionnaire which is completed at the start and end of therapy to measure clinical and reliable change. It measures overall psychological distress across four domains: well-being (4 items), symptoms (12 items), functioning (12 items) and risk (6 items).

The CORE-OM is routinely used within 500 services within the UK (CORE IMS, n.d.). Research investigating the properties of the CORE-OM has found good internal and test-retest reliability (0.75-

0.95), as well as good convergent validity with seven other standardised measures (Evans et al*.,* 2002).

2. World Health Organisation Quality of Life-BREF (WHOQOL-BREF; Skevington et al., 2004)

This scale consists of 26 items which cover physical health, psychological health, social relationships and environment. Each item is scored on a 5 point Likert scale. The WHOQOL-BREF is a shorter version of the original questionnaire and is recommended by WHO for use in clinical trials.

The scale has shown to have excellent psychometric properties of reliability and validity. According to Skevington et al., (2004) the WHOQOL-BREF showed good internal consistency (≥0.8 for physical, psychological and environmental and 0.68 for social relationships) across 23 countries with a total sample size of 11,830.

3. Acceptance and Action Questionnaire II (AAQ-II; Bond, Hayes & Baer et. al, 2011)

The *Acceptance and Action Questionnaire II (AAQ-II)* is a 7-item, uni-dimensional, self-report questionnaire which measures the construct of experiential avoidance/psychological inflexibility (or positively known as acceptance).

The AAQ-II addresses the AAQ-I's problems with obtaining significant alpha levels and has been shown to measure the same concept (*r=.97).* From a total of 2816 participants (across 6 samples), the AAQ-II has good test re-test reliability of .81 - .79 (across 3- and 12-months).

4. Mindfulness Attention Awareness Scale (MAAS; Brown & Ryan, 2003)

The *Mindfulness Attention Awareness Scale (MAAS)* is a 15-item, self-report questionnaire which measures psychological awareness. It has good convergent and discriminant validity and high internal consistency levels ranging from .80 to .90 (Cronbach's alpha).

5. The Cognitive Fusion Questionnaire (CFQ; Gillanders, Bolderston, Bond et, al. 2014)

The *Cognitive Fusion Questionnaire (CFQ)* is a 7-item, self-report questionnaire. It offers a generic assessment of fusion with cognition in general. It shows good factor structure, test re-test reliability (.80) and internal consistency (.88 - .93).

6. ***The Engaged Living Scale (ELS; Trompetter et al., 2013)***

The ELS is a 16-item, self-report questionnaire which measures values and committed action. It is based on two factors; valued living (10 items) and life fulfilment (6 items) and was evaluated using a non-clinical (*N* = 439) and clinical sample (*N* = 238) consisting of chronic pain patients. It shows good construct validity and internal consistency (.87 - .91).

7. ***Dysfunctional Attitudes Scale – Form A (DAS-A; Weissman, 1979)***

The DAS-A is a 40-item, self-report questionnaire that measures rigid, perfectionistic and negative attitudes. Beevers, et al., (2007) found an internal consistency reliability of .84 using 250 patients with depression. They also found that the DAS-A was moderately correlated with other related measures (e.g. *rs* = .33-.49 with the Beck Depression Inventory) and predicted concurrent depression severity.

8. ***The Depression, Anxiety and Stress Scales (DASS-21; Lovibond & Lovibond, 1995)***

The DASS-21 is a 21 item self-report measure consisting of three scales which assess depression, anxiety and stress. Each scale has good reliability (Cronbach α's = 0.88, 0.82 & 0.90 and good convergent and divergent validity. The DASS-21 is recommended for

research purposes and allows both anxiety and depression to be measured within the same questionnaire.

The following information will also be collected:

Demographic Questionnaire (pre-intervention)

This questionnaire will be used to collect demographic information from participants regarding gender, age, education and employment status. Questions about duration of symptoms, number of episodes and previous help sought will also be included.

Treatment fidelity questionnaire (post-intervention)

A treatment fidelity questionnaire will be created for this study to assess adherence to the intervention. Questions will include amount of time spent reading each chapter, engagement in the work (number of weekly tasks completed), alternative treatments tried during the intervention (psychological and pharmaceutical) and basic knowledge assessment.

Sample Size

Mixed ANOVA involves multiple significance tests; the two main effects (time of measurement and treatment condition) and an interaction between time and condition. Within and between subject comparisons are therefore evaluated.

Based on previous research, the anticipated likely effect size is large. An ACT-based self-help study by Fledderus et al., (2012) found large effect sizes of 0.74 and 0.89 (Cohen's d) for the primary outcome of depression. The study compared a manual-based ACT intervention with extensive email support, a manualised ACT intervention to minimal support and a waiting-list control group. Johnston et al., (2010) found medium to large effect sizes 0.54 – 1.16 (Cohen's d; apart from on the Satisfaction with Life Scale which yielded a low effect size) using a self-help book and weekly telephone support for individuals with chronic pain. Carlbring et al., (2013) found a mean within-group effect size of 1.11 (Cohen's d) in an internet-delivered treatment for depression. Meyer (2009) found a within-group medium effect size of .64 (Cohen's d) in a web-based intervention for depression.

G*Power (Version 3.1.9.2) was used to formally compute a sample size calculation.

Using an "a priori" power analysis for "ANOVA: Repeated measures, within-between interaction", the effect size "F" was entered as 0.35 (a large effect size according to Cohen, 1992). Probability was set at 0.05 and power at .80. This yielded a sample size of 20 per condition.

Taking into consideration drop-out rates whilst in the intervention period an estimated 26 people per group (n=52) would be needed (a 30% drop out rate has been presumed). To get the 52 people, 208 people will need to be contacted on the waiting list over the year. This number has been estimated based on a conservative 25% uptake of people who would wish to volunteer within the research.

Confidence in being able to achieve a sample of at least this size:

Within Forth Valley, the Primary Care Clinical Psychology Department receives a high volume of referrals. Of these referrals the majority are suitable for the service. Table 1 highlights the number of clients added to the waiting list each year:

Table 1

The number of referrals each year that are deemed suitable for individual therapy and placed on the waiting list

Year	North Service (Stirling)	South Service (Falkirk)	Combined
2010	386	614	1000
2011	419	683	1102
2012	406	736	1142
2013	421	672	1093

The figures demonstrate a relatively stable number of referrals coming into the service. It is predicted that the same level of referrals will be reached during 2015 and 2016 when recruitment for this study will take place.

Based on 1000 patients coming into the service over a year, inviting up to 208 people to participate in the study accounts for a conservative 21% of the total waiting list which seems achievable.

Analysis

The primary research question:

Demographic data will be examined by using a one-way, between-subjects analysis of variance (ANOVA) to determine any significant differences between groups at baseline.

A mixed 2x2 ANOVA will be used to compare the two means within subjects (measurement time points 1 and 2) and between subjects (treatment condition; intervention or control). This will be followed up by a post hoc Tukey's honestly significant difference (HSD) test and paired t-tests.

The secondary research question:

The secondary hypothesis to be tested is that increases in psychological flexibility will mediate the relationship between intervention and improved quality of life. This will be tested using bootstrapped product of coefficient tests (Hayes, 2013).

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Appendix 8: NHS Ethical Approval for 15/WS/0056

WoSRES
West of Scotland Research Ethics Service

NHS
Greater Glasgow and Clyde

West of Scotland REC 5
Ground Floor - Tennent Building
Western Infirmary
38 Church Street
Glasgow
G11 6NT

Mr Shane Ford

Date 25 March 2015

Dear Mr Ford

Study title: **Evaluating Acceptance and Commitment Therapy (ACT) as a Low-Intensity, Manual-Based, Guided Self-Help Intervention for Anxiety and Depression: A Pilot Study.**
REC reference: **15/WS/0056**
IRAS project ID: **166325**

Thank you for your e-mail of 24 March 2015. I can confirm the REC has received the documents listed below and that these comply with the approval conditions detailed in our letter dated 24 March 2015

Documents received

The documents received were as follows:

Document	*Version*	*Date*
Participant consent form	5	24 March 2015
Participant information sheet (PIS)	5	24 March 2015

Approved documents

The final list of approved documentation for the study is therefore as follows:

Document	*Version*	*Date*
Covering letter on headed paper [Cover Letter]		13 February 2015
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Insurance/Indemnity from The University of Edinburgh]		08 August 2014
GP/consultant information sheets or letters [Letter to GP]	2	22 January 2015

Document	*Version*	*Date*
Letters of invitation to participant [Letter of Participation]	1	11 February 2015
Non-validated questionnaire [Getting to know you questionnaire]		
Other [Public Liability Insurance]		16 June 2014
Other [ACT Manual]		
Other [Manual Critiques]		
Participant consent form	5	24 March 2015
Participant information sheet (PIS)	5	24 March 2015
REC Application Form [REC_Form_26022015]		26 February 2015
Research protocol or project proposal [Thesis Research Protocol]	3	03 February 2015
Summary CV for Chief Investigator (CI) [CV]		
Summary CV for supervisor (student research) [Dr David Gillander's CV (Academic Supervisor)]		
Validated questionnaire [AAQ-II]		
Validated questionnaire [Clinical Outcome in Routine Evluation Measure 34]		
Validated questionnaire [Cognitive Fusion Questionnaire]		
Validated questionnaire [Depression Anxiety Stress Scale]		
Validated questionnaire [Dysfunctional Attitudes Scale]		
Validated questionnaire [Engaged living scale psychometrics]		
Validated questionnaire [Mindfulness Attention Awareness Scale]		
Validated questionnaire [World Health Organisation Quality of Life BREF]		

You should ensure that the sponsor has a copy of the final documentation for the study. It is the sponsor's responsibility to ensure that the documentation is made available to R&D offices at all participating sites.

15/WS/0056 **Please quote this number on all correspondence**

Yours sincerely

R Gallacher

Rose Gallacher
Assistant Administrator

Copy to: *Ms Jo-Anne Robertson, University of Edinburgh*
Ms Rosemary Wilson, NHS Forth Valley

WoSRES
West of Scotland Research Ethics Service

NHS
Greater Glasgow and Clyde

West of Scotland REC 5
Ground Floor - Tennent Building
Western Infirmary
38 Church Street
Glasgow
G11 6NT

Mr Shane Ford

Date 24 March 2015

Dear Mr Ford

Study title: **Evaluating Acceptance and Commitment Therapy (ACT) as a Low-Intensity, Manual-Based, Guided Self-Help Intervention for Anxiety and Depression: A Pilot Study.**
REC reference: **15/WS/0056**
IRAS project ID: **166325**

The Research Ethics Committee reviewed the above application at the meeting held on 18 March 2015. Thank you for attending to discuss the application.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact the REC Manager Mrs Sharon Macgregor, WoSREC5@ggc.scot.nhs.uk. Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

Ethical opinion

The members of the Committee present gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below. .

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

1. The following minor changes should be made to the Participant Information Sheet:
a) In the "Why have I been invited?" section, "whom" should be changed to "who".
b) In the "Do I have to take part?" section, in line 3 "consent form signed" should be changed to "signed consent form"
c) In the last line of the same section "standard of" should be removed.
d) In the "What will happen to me..?" section, line 7 and 33, "*stamped* addressed envelope" should be changed to "pre-stamped…".

e) In paragraph 2 of the same section, line 12, "posting" should be changed to "returning".

Although not a condition of approval, the sample size calculation should be checked again as this is incorrect.

You should notify the REC in writing once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which can be made available to host organisations to facilitate their permission for the study. Failure to provide the final versions to the REC may cause delay in obtaining permissions.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations.

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database. This should be before the first participant is recruited but no later than 6 weeks after recruitment of the first participant.

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from NRES. Guidance on where to register is provided on the HRA website.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

NHS Sites

The favourable opinion applies to all NHS sites taking part in the study taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Summary of discussion at the meeting (for information only)

Social or scientific value; scientific design and conduct of the study

It was noted that the sample size calculation was incorrect and the researcher was advised to have the calculation checked again. Rather than 26 people in each group, a 30% drop out rate would mean groups of 28 or 29. The researchers are not required to respond to the Committee about this issue.

Informed consent process and the adequacy and completeness of participant information

Minor changes in the Participant Information Sheet were noted and require correction.

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Covering letter on headed paper [Cover Letter]		13 February 2015
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Insurance/Indemnity from The University of Edinburgh]		08 August 2014
GP/consultant information sheets or letters [Letter to GP]	2	22 January 2015
Letters of invitation to participant [Letter of Participation]	1	11 February 2015
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Other [Manual Critiques]		
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Participant information sheet (PIS) [Participant Information Sheet]	4	06 February 2015
REC Application Form [REC_Form_26022015]		26 February 2015
Research protocol or project proposal [Thesis Research Protocol]	3	03 February 2015
Summary CV for Chief Investigator (CI) [CV]		
Summary CV for supervisor (student research) [Dr David Gillander's CV (Academic Supervisor)]		
Validated questionnaire [AAQ-II]		
Validated questionnaire [Clinical Outcome in Routine Evluation Measure 34]		
Validated questionnaire [Cognitive Fusion Questionnaire]		
Validated questionnaire [Depression Anxiety Stress Scale]		
Validated questionnaire [Dysfunctional Attitudes Scale]		
Validated questionnaire [Engaged living scale psychometrics]		
Validated questionnaire [Mindfulness Attention Awareness Scale]		
Validated questionnaire [World Health Organisation Quality of Life BREF]		

Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

After ethical review

Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Training

We are pleased to welcome researchers and R&D staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

15/WS/0056	**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project.

Yours sincerely

SMacgregor

for
Dr Gregory Ofili
Chair

Enclosures: List of names and professions of members who were present at the meeting and those who submitted written comments

"After ethical review – guidance for researchers"

Copy to: Ms Jo-Anne Robertson, University of Edinburgh
Ms Rosemary Wilson, NHS Forth Valley

West of Scotland REC 5

Attendance at Committee meeting on 18 March 2015

Committee Members:

Name	*Profession*	*Present*	*Notes*
Dr Stewart Campbell	Consultant Physician & Gastroenterologist	Yes	
Dr Roddy Chapman	Consultant Anaesthetist	No	
Dr James Curran	GP	No	
Dr Gillian Harold	Consultant Radiologist	No	
Dr Gillian Kerr	Consultant Physician	Yes	
Dr Ahmed Khan	Consultant Psychiatrist	Yes	
Professor Eddie McKenzie	Statistician	Yes	
Canon Matt McManus	Parish Priest	Yes	
Ms Janis Munro	Key Account Manager	Yes	
Dr Gregory Ofili	Consultant Gynaecologist (CHAIR)	Yes	
Mrs June Russell	Retired (Research Chemist)	No	
Mr Charles Sargent	Retired	Yes	
Dr Marcel Strauss	Consultant Radiologist	Yes	
Mrs Liz Tregonning	Retired (Special Needs Teacher)	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Dr Judith Godden	Scientific Officer/Manager
Mrs Sharon Macgregor	Co-ordinator

Appendix 9: Published protocol for study (NCT02449759) on Clinicaltrials.gov

An ACT Manual-based, Guided Self-help Intervention Pilot (ACT)

This study is currently recruiting participants. (see Contacts and Locations)

Verified November 2016 by University of Edinburgh

Sponsor:
University of Edinburgh

Information provided by (Responsible Party):
University of Edinburgh

ClinicalTrials.gov Identifier:
NCT02449759

First received: April 29, 2015
Last updated: December 7, 2016
Last verified: November 2016
History of Changes

Purpose

This study aims to evaluate the effectiveness of a guided self-help intervention using Acceptance and Commitment Therapy (ACT). Half of the participants will receive the self-help manual whilst on a waiting list for individual therapy, while the other half will remain on a waiting list and not receive the manual. This study is looking specifically at individuals with mild to moderate anxiety and/or depression.

Condition	Intervention
Anxiety Depression	Behavioral: ACT Intervention Group

Study Type: Interventional
Study Design: Allocation: Randomized
Intervention Model: Parallel Assignment
Masking: Single Blind (Investigator)
Primary Purpose: Treatment

Official Title: Evaluating Acceptance and Commitment Therapy as a Low-intensity, Manual-based, Guided Self-help Intervention for Anxiety and Depression: A Pilot Study

Resource links provided by NLM:

MedlinePlus related topics: Anxiety

U.S. FDA Resources

Further study details as provided by University of Edinburgh:

Primary Outcome Measures:

- Change is being assessed using the Quality of Life BREF (WHOQOLBREF; Skevington et al., 2004) questionnaire [Time Frame: Baseline and 6 weeks]

  26-item self-report questionnaire

Secondary Outcome Measures:

- Change is being assessed using the Acceptance and Action Questionnaire II (AAQII; Bond, Hayes & Baer et. al, 2011). [Time Frame: Baseline and 6 weeks]

  A 7-item, unidimensional, self-report questionnaire which measures the construct of experiential avoidance/psychological inflexibility

Estimated Enrollment: 52
Study Start Date: April 2015
Estimated Study Completion Date: May 2017
Estimated Primary Completion Date: May 2017 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: ACT Intervention Group This group will receive an ACT self-help manual to be completed over the course of 6 weeks. They will also receive two brief telephone calls during the reading of the manual by a member of the research team.	Behavioral: ACT Intervention Group A six chapter, 58 page self-help manual based on the principles of Acceptance and Commitment Therapy
No Intervention: Control Group This group will receive no intervention	

Detailed Description:

Many patients are offered written self-help material as a stage 1 (low intensity) intervention for anxiety and/or depression, as recommended by the United Kingdom's National Institute for Clinical Excellence's pathways framework (http://pathways.nice.org.uk/).

Acceptance and Commitment Therapy (ACT) is an emerging therapy that has been shown to help patients with mild to moderate anxiety and/or depression in therapist-led individual and group treatments. However, few studies have shown how effective ACT is in the form of a low-intensity, guided self-help intervention.

This study seeks to find out whether an ACT-based manual, sent to patients with anxiety and/or depression, increases their ability to effectively manage their difficulties and improve their quality of life. Participants on a primary care mental health waiting list will be invited to take part in this study.

Eligible participants will be randomly allocated to one of two groups: the ACT intervention or waiting list as usual. Participants receiving the ACT intervention will be posted a manual and will be asked to read a chapter each week for six weeks. A member of the research team will also phone them on two occasions to support their use of the manual, trouble shoot any difficulties and provide encouragement. All participants will be asked to complete nine, short questionnaires sent through the post prior to and after six weeks of self-help.

By comparing the results the study will demonstrate whether the ACT intervention is effective compared to wait list as usual.

Eligibility

Ages Eligible for Study: 18 Years to 65 Years (Adult)
Sexes Eligible for Study: All
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- On the primary care waiting list for individual therapy
- Anxiety or depression/low mood assessed using the Depression, Anxiety and Stress Scales (DASS21). Those with mild to moderate (≥ 4 and ≤ 7) mixed anxiety (including panic, agoraphobia, obsessive compulsive disorder, generalised anxiety disorder and phobias) or depressive/low mood (including dysthymia; ≥ 5 and ≤ 10) will be included.
- For those participants presenting with both anxiety and depression, at least one must reach the minimum cut off score and neither should exceed the maximum cut-off score.
- Adequate English ability
- Able to give informed consent

Exclusion Criteria:

- High suicide risk (as indicated with a risk score of >0.3 on the Clinical Outcomes in Routine Evaluation questionnaire; CORE-34
- Participants that have been flagged at the referral meeting to receive specialised individual therapy (e.g. schema-focussed therapy)
- Medication change within the last three months*
- Currently receiving or received psychological help within the last 6 months using a Cognitive Behavioural Therapy or ACT modality (e.g. Beating the Blues, Anxiety Management Groups, Mindfulness, Individual therapy)
- Currently taking part in another research study
- Intellectual impairment (e.g. a learning disability)
- Referral for a primary diagnosis, other than anxiety/depression, that would significantly over arch any work focusing on anxiety/depression even if the above criteria is met for anxiety/depression (e.g. an eating disorder whereby the stated symptoms: cognitions, physical sensations, emotions and behaviours, are orientated solely around food).
  - Those individuals who have started or changed medication within the last 3 months will still be eligible to participate, but will be put on hold until this time period has elapsed. They will be informed of this and told that they may not be entered into the trial if recruitment targets are met or individual treatment becomes available (the waiting list will be reviewed at the time).

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT02449759

Contacts

Contact: Shane A Ford 01324 614347 shane.ford@nhs.net

Locations

United Kingdom

Adult Psychology Department **Recruiting**
Falkirk, Stirlingshire, United Kingdom, FK1 5QE
Contact: Shane A Ford shane.ford@nhs.net
Contact: Sally Rankine

Sponsors and Collaborators

University of Edinburgh

Investigators

Principal Investigator: Shane A Ford National Health Service, United Kingdom

More Information

Additional Information:

National Institute for Clinical Excellence's pathways framework

Publications:

Skevington SM, Lotfy M, O'Connell KA; WHOQOL Group.. The World Health Organization's WHOQOL-BREF quality of life assessment: psychometric properties and results of the international field trial. A report from the WHOQOL group. Qual Life Res. 2004 Mar;13(2):299-310.

Bond FW, Hayes SC, Baer RA, Carpenter KM, Guenole N, Orcutt HK, Waltz T, Zettle RD. Preliminary psychometric properties of the Acceptance and Action Questionnaire-II: a revised measure of psychological inflexibility and experiential avoidance. Behav Ther. 2011 Dec;42(4):676-88. doi: 10.1016/j.beth.2011.03.007.

Responsible Party: University of Edinburgh
ClinicalTrials.gov Identifier: NCT02449759 History of Changes
Other Study ID Numbers: 166325
Study First Received: April 29, 2015
Last Updated: December 7, 2016
Individual Participant Data
Plan to Share IPD: No

Additional relevant MeSH terms:
Depression
Depressive Disorder
Behavioral Symptoms
Mood Disorders
Mental Disorders

ClinicalTrials.gov processed this record on March 01, 2017

Appendix 10: Participant Information Sheet

Participant Information Sheet

Study Title:

Evaluating Acceptance and Commitment Therapy in the form of a Self-Help Manual for Anxiety and/or Depression with Minimal Telephone Support.

An Invitation…

We would like to invite you to take part in our research study. Before you decide we would like you to understand why the research is being done and what it would involve of you. **Please read this information sheet carefully before you decide whether you wish to take part.** If you would like to contact someone to discuss the research further you can find our contact details below.

What is the purpose of the study?

Research has shown that guided self-help materials, such as books, can be effective in reducing depression and anxiety. We would like to trial a new self-help manual to see whether individuals benefit from it. The manual is based on a fairly new therapy called Acceptance and Commitment Therapy (ACT). If this study shows ACT to be effective it may allow us to provide such materials to individuals dealing with anxiety/depression in the future.

Why have I been invited?

You have been invited to take part because you have been referred to the Adult Psychology Department at Falkirk Community Hospital or Stirling Community Hospital. This invitation is being passed on to anyone who has opted in to be seen within the department.

Who is carrying out this study?

This research is being undertaken in conjunction with the University of Edinburgh as part of a Clinical Psychology Doctorate thesis. The Principal Researcher (Mr Shane Ford) is employed by NHS Forth Valley as a Trainee Clinical Psychologist. This study has been reviewed by academic staff at the University of Edinburgh as well as clinical staff at the Adult Psychology Department within NHS Forth Valley. It has been approved by the NHS Research and Development department in Forth Valley and has been subject to review by a research ethics committee.

Do I have to take part?

No, it is up to you whether or not you decide to join the study. This information sheet describes the study in detail and the requirements needed from you. If you agree to take part, we will ask you to sign the consent form. By sending back the signed consent form this implies that you are voluntarily wishing to take part in the study. Please return your signed consent form within one week of receiving it. Once returned, the Principal Researcher (Mr Shane Ford) will also sign to say you have voluntarily consented into the study. You are free to withdraw from the study at any time, without giving a reason. This would not affect the care you receive.

What will happen to me if I take part?

If you choose to take part you will be asked to fill out the questionnaires sent to you through the post. There are nine in total and it will take approximately 20 minutes to complete them. You don't have to complete all nine at the same time. The questionnaires will ask about a range of different things including information regarding your age, gender, ethnicity, information about your difficulties (e.g. low mood, anxiety etc) and how you currently manage these difficulties. You will be asked to post these back to the department in a pre-stamped envelope.

When we receive your questionnaires you may then receive a self-help manual through the post with instructions on how and when to read it. We do not know how effective the manual will be. To find out we need to compare it with individuals who will not receive the manual. To do this we put people into two groups. To try and make sure the groups are the same to start with, each patient is put into a group by chance (randomly). One group will not receive a manual but will still be asked to fill out the questionnaires. The other group will receive the manual to read, as well as fill out the questionnaires. You have a 50% chance of receiving a manual. We will compare the results of the two groups to see whether the manual had any benefit. The manual will be posted within two weeks of you sending the enclosed consent form and questionnaires back to us. If you do not receive a manual within this time you can assume that you have been allocated to the group not receiving a manual. We will still post you another set of questionnaires in 6 weeks.

If you receive the manual you will be asked to read a chapter of it each week and put what you have learned into practice. Each chapter is only 5-8 pages and takes approximately 20 minutes to read. There are six chapters in the manual so it will take a total of six weeks to complete. During these six weeks a member of the team will phone you on two occasions to check you understand the manual and answer any questions you may have. These telephone calls should only take a few minutes of your time. If you do not receive a manual you will not be contacted by telephone during the six weeks since you posted your questionnaires. You can still, however, contact the research team yourself should you have any questions related to the study.

After the six weeks is over everyone will be posted the same set of questionnaires that you received at the start. You will be asked to complete these questionnaires again and post them back in the pre-stamped envelope provided. We will then see how effective the manual was.

In summary, you will be asked to fill out two sets of questionnaires, six weeks apart. Should you be assigned a manual, you will also be asked to read a chapter of this each week (which will take approximately 20 minutes) for six weeks and will receive two telephone calls.

Expenses

All postage will be paid for including stamped addressed envelopes to the department so that you can return your questionnaires to us for free. If you receive the manual it is free of charge and it's yours to keep. We will also call you so that you incur no cost. Your time is voluntary and you can withdraw from the research at any time.

What are the possible disadvantages and risks of taking part?

The whole project can be done from the comfort of your own home. It will however take up some of your time so please consider this before deciding to take part.

The questionnaires and manuals ask personal questions relating to your difficulties. For some, this can bring up certain emotions that feel uncomfortable or even distressing. This is normal and is to be expected when thinking about personal and difficult topics. However, it is possible that you may become very distressed. The researcher can be contacted during working hours and is trained to support people in distress. You can also contact telephone support services which are mentioned in the booklet and also below:

Samaritans 08457 909090

The Samaritans provide a confidential support line for people feeling in distress or despair. You can talk to somebody who will help you explore different options and help you come to your own decisions.

SANE 08457 678000

SANE runs an out-of-hours mental health help-line (6pm—11pm) offering specialist emotional support and information to anyone affected by mental illness, including family, friends and carers.

NHS 24 111

This service provides comprehensive up-to-date medical information from NHS staff for people within Scotland. This telephone-based service can answer your questions about your health and offer advice.

Breathing Space 0800 83 85 87

This free and confidential telephone service consists of experienced advisors who will listen to you and provide information and advice.

What are the possible benefits of taking part?

There is no direct benefit to participating in the study, however research has shown that the therapy used within the manual has been effective in other self-help studies, groups and individual therapy. The information we get from this study may also help improve the treatment of people with depression and/or anxiety in the future.

What happens after the research stops?

Once you have completed the study you will continue to stay on the waiting list for individual therapy within the department. Participating in this study will **not** increase your wait for individual therapy. You will remain in the same place on the waiting list and a member of the team will contact you when a place becomes available. If a place for individual therapy becomes available before you reach the end of the study your participation will stop prematurely as individual therapy with a therapist would be considered the treatment of choice.

What if there is a problem?

Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. If you have a concern about any aspect of the study, you should speak to the complaints department. To do this please phone the NHS Forth Valley Patient Relations and Complaints Service on 01324 566660.

Will my taking part in the study be kept confidential?

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. All information during the course of the research will be kept strictly confidential. Your questionnaires will be stored securely and coded so that in the unlikely event that they are lost or stolen they will be unidentifiable. Only the researcher and clinical supervisor will have access to your identifiable data. Regulatory authorities, the Sponsor and the Research and Development Department may seek access to the data for monitoring of the quality of the research.

If there are any concerns about your wellbeing or your safety from the responses you put on the questionnaires we will seek to contact you. If we have serious concerns we may contact your GP.

Involvement of the General Practitioner (GP)

Your GP will be notified by letter that you are taking part in this study. He/she will not be given access your questionnaires unless your answers indicate significant risk to yourself or others.

What will happen if I don't want to carry on with the study?

If you do not wish to carry on with the study your data collected up to your withdrawal may be still be used. We would appreciate that you let us know of your intention not to continue with the study. However, if you do not wish to do this we may call you at the end of the study to follow up on any questionnaires that have not been returned. You can let us know at this point that you do not wish to participate further.

What will happen to the results of the study?

The results are intended to be published in a psychological research journal to inform others. You can request a copy of the general results by contacting the department (please note it could take several years before the results are published). Your individual results can not be obtained as the data is analysed as a group, not separately.

Contact Details:

You can contact the principal researcher on **01324 614347**. This number will put you through to reception. You should ask to speak to Shane Ford. If Shane is not available you can leave a message or call back at another time. Office hours are 9.00am – 5.00pm, Monday to Friday.

If you wish to speak to the clinical supervisor please contact Dr Sally Rankine, Consultant Clinical Psychologist on 01324 614347.

If you wish to contact someone in the department who isn't part of this research to discuss participating in research in general please ring 01324 614347 and ask to speak to Dr Jennifer Borthwick.

THANK YOU FOR TAKING THE TIME TO READ THROUGH THIS INFORMATION SHEET

Appendix 11: Consent Form

Psychology Services

NHS Forth Valley
Psychology Services
Falkirk Community Hospital
Major's Loan
FALKIRK, FK5 4QE

Patient Identification Number for this trial: _____

CONSENT FORM

Title of Project: Evaluating Acceptance and Commitment Therapy (ACT) as a Low-Intensity, Manual-Based, Guided Self-Help Intervention for Anxiety and Depression: A Pilot Study.

Name of Researcher: Mr Shane Ford

Please initial each box

1. I confirm that I have read and understand the information sheet dated 24/03/2015 (version 5) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. ☐

3. I understand that relevant sections of my medical notes and data collected during the study, may be looked at by the named researcher above, individuals from regulatory authorities or from the sponsor (University of Edinburgh) or from NHS Forth Valley where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records. ☐

4. I agree to my GP being informed of my participation in the study. ☐

5. I agree to take part in the above study. ☐

_____	_____	_____
Name of Patient	Date	Signature
_____	_____	_____
Name of person taking consent	Date	Signature

When completed: 1 for participant; 1 for researcher site file; 1 (original) to be kept in medical notes. Page 1 of 1

Appendix 12: CONSORT 2010 checklist of information to include when reporting a randomised trial

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	75
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	75
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	76
	2b	Specific objectives or hypotheses	81
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	82
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	84
Participants	4a	Eligibility criteria for participants	83
	4b	Settings and locations where the data were collected	82
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	86
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	84
	6b	Any changes to trial outcomes after the trial commenced, with reasons	n/a
Sample size	7a	How sample size was determined	84
	7b	When applicable, explanation of any interim analyses and stopping guidelines	n/a

Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	89
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	89
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	89
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	89
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	89
	11b	If relevant, description of the similarity of interventions	n/a
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	90
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	90
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	90
	13b	For each group, losses and exclusions after randomisation, together with reasons	90
Recruitment	14a	Dates defining the periods of recruitment and follow-up	82
	14b	Why the trial ended or was stopped	n/a
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	93

Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	96
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	100
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	100
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	n/a
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	n/a
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	105
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	106
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	104
Other information			
Registration	23	Registration number and name of trial registry	82
Protocol	24	Where the full trial protocol can be accessed, if available	Appendix 7
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	n/a

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

Appendix 13: Demographic Questionnaire

SECTION 1

Participant ID Number _____

Getting To Know You Questionnaire

Thank you for taking part in this study. Below are a series of questions relating to yourself and how you have been feeling over the last few weeks. **Before you answer these questions please read the participant information sheet carefully**. If you are happy with what this study entails and you have no further questions, please sign the enclosed consent form and begin answering the questions below. You don't have to answer the questions all at once. If you need a break please make sure you stop at the end of a section, rather than in the middle of a set of questions. If you have any further questions about the study, please contact the researcher, Mr Shane Ford, on [redacted]

Please write clearly so we can input your answers as accurately as possible

Today's date ___ /___ /_____

Your telephone number (home or mobile) _____

Can we leave a message on your answering machine should we not be able to reach you? YES ☐ NO ☐

What language do you speak? (e.g. English, Chinese, Italian) _____

How would you classify yourself?

- ☐ Black or African American
- ☐ Native American or American Indian
- ☐ Asian / Pacific Islander

Other: _____

What is the highest level of education you have completed?

- ☐ College
- ☐ University (degree level)
- ☐ University (masters level)
- ☐ University (doctoral level)

Other: _____

What is your current marital status?

- ☐ Divorced
- ☐ Living with another
- ☐ Married
- ☐ Separated
- ☐ Single
- ☐ Widowed

Which of the following categories best describes you?

- ☐ Student
- ☐ Part-time employed *(less than 35 hours a week)*
- ☐ Full-time employed *(more than 35 hours a week)*
- ☐ Not employed
- ☐ Homemaker
- ☐ Other

Page 1 of 2

Getting to know you questionnaire. 06/01/2015. V2.

Page 2 of

Getting to know you questionnaire. 06/01/2015. V2.

ID Number _____

Do you smoke? ☐ Yes ☐ No

If yes: How many cigarettes do you smoke per *week*?

_____

Do you drink alcohol? ☐ Yes ☐ No

If yes: How often do you drink?

Once a month ☐

Once a fortnight ☐

Once a week ☐

Up to 3 times a week ☐

Every day of the week ☐

What is your annual household income before tax?

(please circle)

Below £10,000 | £35,001 - £40,000

£10,001 - £15,000 | £40,001 - £45,000

£15,001 - £20,000 | £45,001 - £50,000

£20,001 - £25,000 | £51,001 - £55,000

£25,001 - £30,000 | £55,000+

£30,001 - £35,000

How many children under 18 live in your household?

☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5

What would you say your presenting problems are? (Tick as many as you wish)

☐ Anxiety (including social anxiety)

☐ Depression / Low mood

☐ Panic Attacks

☐ Obsessions / Compulsions (OCD)

☐ Agoraphobia (fear of going outside of your home)

☐ Eating issues (anorexia, bulimia, binge eating)

☐ Trauma (including Post Traumatic Stress Disorder, PTSD)

☐ Schizophrenia/Psychosis (e.g. hearing voices, seeing things)

Now circle what you believe to be your main problem from the list above (this is if you have ticked more than one).

How long would you say you have been experiencing these problems?

☐ 6 months or less ☐ One year ☐ Two years ☐ 3 – 5 years ☐ 6 – 10 years ☐ 11+ years

Have you been diagnosed with any of the following?

☐ Autism / Asperger's / Autistic Spectrum Disorder

☐ A learning disability

☐ Significant memory difficulties (e.g. Dementia)

Do you have any physical health problems?

(e.g. asthma, diabetes, chronic pain, IBS)

_____

_____

_____

Have you received any help for your difficulties before?

(e.g. counselling, psychology, self-help, Beating the Blues)

_____

_____

_____

Are you taking medication for your current difficulty?

☐ Yes ☐ No

If yes: Have you changed your medication in the last 3 months? (Including starting or stopping medication)

☐ Yes ☐ No

How would you rate your reading and writing ability?

Very good Good Average Poor Very poor

Do you anticipate any significant changes in the next two months? (e.g. house move, having a baby, job change)

_____

Appendix 15: Set list of questions during telephone calls

1. How far have you read up to?
2. How did you find the completed chapters?
3. Was there anything that particularly stood out to you?
4. Was there anything that you did not understand?
5. Did you manage to practice the end of chapter exercises?
6. How often did you practice and how did you find these?
7. How has reading this manual changed the way you think about your difficulties?
8. Do you have any further questions?
9. Are you happy to continue reading the manual?

Appendix 16: Completer data including mixed ANOVA results

Outcome measure	ACT (n = 12)		Control (n = 15)		Group effect	Main effect of time	Main effect of group
	M	*(SD)*	*M*	*(SD)*	F (1, 25), p, $\eta 2$	F (1, 25), p, $\eta 2$	F (1, 25), p, $\eta 2$
Primary outcome							
QoL							
Baseline	70.75	9.84	78.06	10.36	7.595, .011, .233	1.101, .304, .042	.626, .436, .024
Post-treatment	76.25	14.54	75.60	11.05			
Secondary outcomes							
CORE-34							
Baseline	62.83	11.46	63.86	15.98	.636, .433, .025	1.593, .219, .060	.658, .425, .026
Post-treatment	53.66	23.03	61.80	21.34			
DASS - depression							
Baseline	23.50	10.02	22.93	7.62	.198, .660, .008	3.75, .064, .131	.002, .956, .001
Post-treatment	19.66	11.62	20.53	9.81			
DASS - anxiety							
Baseline	15.33	5.92	16.66	8.19	.136, .716, .005	.215, .647, .009	.382, .542, .015
Post-treatment	14.16	6.57	16.53	11.45			
DASS - stress							
Baseline	19.16	6.17	24.26	7.00	2.573, .121, .093	.053, .821, .002	1.294, .266, .049
Post-treatment	21.83	7.55	22.26	8.20			
ELS							
Baseline	29.72	11.15	26.29	8.87	.405, .530, .016	4.671, .040, .157	.041, .842, .002
Post-treatment	31.32	5.04	32.12	7.36			
MAAS							
Baseline	50.75	11.15	48.46	13.03	.930, .763, .004	.075, .786, .003	.149, .703, .006
Post-treatment	49.50	11.82	48.35	12.49			
CFQ							
Baseline	33.66	6.93	34.06	9.28	.142, .710, .006	2.087, .161, .077	.097, .758, .004
Post-treatment	31.16	7.24	32.60	9.24			

Effect size conventions for $\eta 2$ are: small > .01, medium >.06 and large >.14 (Lackens, 2013)

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